Established since 2016

케이바이오솔루션 FDA, MDR CE 인증 컨설팅, 임상시험 CRO 전문기업

2023-04-27

케이바이오솔루션 소개자료

KBIO Solutions

㈜ 케이바이오 솔루션

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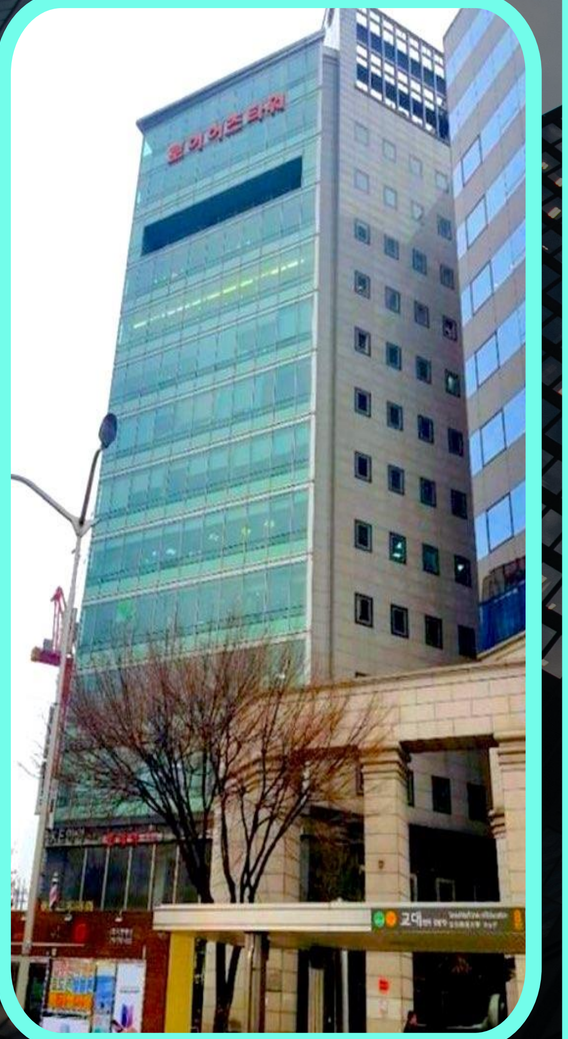
KBIO Office

케이바이오솔루션: FDA, CE 전문 컨설팅 및 CRO 임상시험수탁관리 회사: 서울 교대역 사거리 로이어즈타워에 위치



KBIO MDR 컨설팅팀

케이바이오솔루션: FDA, MDR 컨설팅 및 CRO 임상시험수탁관리 회사

KBIO Office

케이바이오솔루션: FDA, MDR 컨설팅 및 CRO 임상시험수탁관리 회사
서울 교대역 사거리 KBIO 사무소

케이바이오솔루션은 2016년 9월 설립되어
50여개 이상의 의료기기 기업들의 미국,
유럽, 식약처 인허가 컨설팅 및, 한국 및
미국에서 임상시험 CRO 서비스를 제공하고 있습니다.

회사 연혁

2016.09.19: 케이바이오솔루션 설립

2017: 5개 의료기기 제조사 인허가 컨설팅 수행

2018: 8개 의료기기 제조사 인허가/임상 컨설팅 수행

2019: 30개 의료기기 제조사 인허가 컨설팅 수행,
서울 사무소 확장이전

2020: 40개 의료기기 제조사 인허가/임상 컨설팅 수행

2021: 미국 실리콘밸리 판매스토어,
자매사 (주)케이바이오 테라퓨틱스 설립,

2022 8월 서울사무소 확장이전

KBIO 2023 KIMES 전시회

케이바이오솔루션: FDA, MDR 컨설팅 및 CRO 임상시험수탁관리 회사

2022.03.23-26 코엑스 전시회 참여

KBIO 2023 KIMES 전시회

케이바이오솔루션: FDA, MDR 컨설팅
및 CRO 임상시험수탁관리 회사로
2022.03.23 - 26 코엑스 전시회 부스 4개 참여

KBIO 2023 KIMES 전시회

KIMES 2023 제38회 국제의료기기+병원설비전시회

세미나 주제 신청서

* 하기 내용은 전시회 홈페이지 및 홍보물이 기재되오니 정확히 작성해주시기 바랍니다.

대주제 (* 대주제는 외국인 강연에만 기재하시면 됩니다.)					
국문	의료기기 EU MDR, FDA 510(k) 인허가 전략 및 임상시험 세미나				
영문	Medical Device EU MDR, FDA 510(k) Registration Strategy & Clinical Trial Plan				
[일시]	3월 24일 09:00am ~06:00pm	[주관] (국/영문)	케이바이오솔루션 KBIO Solutions	[장소]	사무국에서 기입

1	소주제 및 강사					
	소주제	의료기기 글로벌 시장 분석, MDR CE, FDA 510(k) 주요 요건 설명				
	[강사]	소속	이름	직책	[시간]	09:00~10:00
		케이바이오솔루션	강경윤	대표		
	Topic	Medical Device Global Market Analysis, MDR & 510(k) Key Requirements				
	[Speaker]	Company	Name	Job Title	[Time]	09:00~10:00
		KBIO Solutions	Kyungyoon Kang	CEO		
2	소주제 및 강사					
	소주제	FDA 510(k) 동등비교 및 FDA 성능, 안전성 시험 전략				
	[강사]	소속	이름	직책	[시간]	10:10~11:00
		케이바이오솔루션	강경윤	대표		
	Topic	FDA 510(k) Substantial Equivalence, Performance & Safety Testing Strategy				
	[Speaker]	Company	Name	Job Title	[Time]	10:10~11:00
		KBIO Solutions	Kyungyoon Kang	CEO		
3	소주제 및 강사					
	소주제	임상시험				
	[강사]	소속	이름	직책	[시간]	11:10~11:30
		케이바이오솔루션	미카엘 헬스트란드	대리		
	Topic	Clinical Trial Management-FDA IDE				
	[Speaker]	Company	Name	Job Title	[Time]	11:10~11:30
		KBIO Solutions	Mikael Hellstrand	Manager		
4	소주제 및 강사					
	소주제	MDR CE, FDA 510(k), GMP 관련 Q&A 질의 응답 세션				
	[강사]	소속	이름	직책	[시간]	11:30~12:00
		케이바이오솔루션	강경윤	대표		
	Topic	MDR CE, FDA 510(k), GMP Q&A Session				
	[Speaker]	Company	Name	Job Title	[Time]	11:30~12:00
		KBIO Solutions	Kyungyoon Kang	CEO		

KIMES 2023 제38회 국제의료기기+병원설비전시회

세미나 주제 신청서

5	소주제 및 강사					
	소주제	EU MDR 파일작성 실무				
	[강사]	소속	이름	직책	[시간]	01:00~01:20
		케이바이오솔루션	박지안, 브랜든 그린	주임		
	Topic	EU MDR Documentation Practice				
	[Speaker]	Company	Name	Job Title	[Time]	01:00~01:20
		KBIO Solutions	Jian Park, Brandon Green	Manager		
6	소주제 및 강사					
	소주제	MDR 파일작성-Tech Doc, GSPR, Risk Management, PMS, IFU				
	[강사]	소속	이름	직책	[시간]	01:20~2:00
		케이바이오솔루션	강경윤	대표		
	Topic	MDR Documentation-Tech Doc, GSPR, Risk Management, PMS, IFU				
	[Speaker]	Company	Name	Job Title	[Time]	01:20~02:00
		KBIO Solutions	Kyungyoon Kang	CEO		
7	소주제 및 강사					
	소주제	EU MDR 2017/745 적용되는 MDCG 가이던스 설명				
	[강사]	소속	이름	직책	[시간]	02:10~03:00
		케이바이오솔루션	안유진	과장		
	Topic	EU MDR 2017/745 MDCG Guidance Review				
	[Speaker]	Company	Name	Job Title	[Time]	02:10~03:00
		KBIO Solutions	Yujin Ahn	Senior Manager		
8	소주제 및 강사					
	소주제	MDR 임상평가보고서 Clinical Evaluation Report, 사후임상관리 PMCF작성				
	[강사]	소속	이름	직책	[시간]	03:10~04:00
		케이바이오솔루션	강경윤	대표		
	Topic	How to Write MDR Clinical Evaluation Report and PMCF Report				
	[Speaker]	Company	Name	Job Title	[Time]	03:10~04:00
		KBIO Solutions	Kyungyoon Kang	CEO		
9	소주제 및 강사					
	소주제	의료기기 임상시험 설계 전략				
	[강사]	소속	이름	직책	[시간]	04:10~05:10
		케이바이오솔루션	강경윤	대표		
	Topic	Medical Device-Clinical Study Development Strategy				
	[Speaker]	Company	Name	Job Title	[Time]	04:10~05:10
		KBIO Solutions	Kyungyoon Kang	CEO		

케이바이오솔루션: FDA, MDR 컨설팅 및 CRO 임상시험수탁관리 회사로

2022.03.24 코엑스 세미나 개최

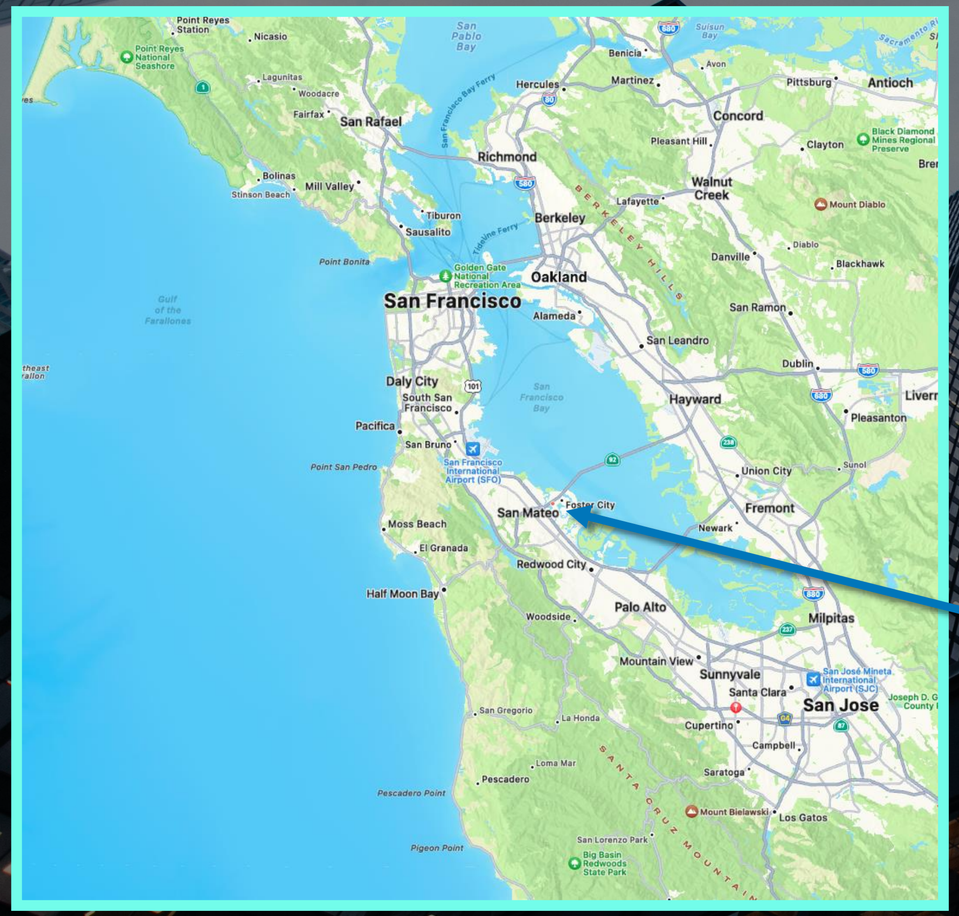
국내 컨설팅사로는 유일하게
미국 캘리포니아 컨설팅 법인을 운영하고 있는 KBIO 미국법인 위치:

미국 주요 바이오 기업들이 입주해있는 실리콘밸리 바이오단지에 헬스케어 카페 센터

KBIO 실리콘밸리 바이오단지 헬스케어 카페 스토어:

Suite 111, 1820 Gateway Drive, San Mateo, California 94404

국내 컨설팅사로는 유일하게
미국 캘리포니아 법인을 운영하고 있는 KBIO USA



미국 캘리포니아 현지 법인 운영을 바탕으로

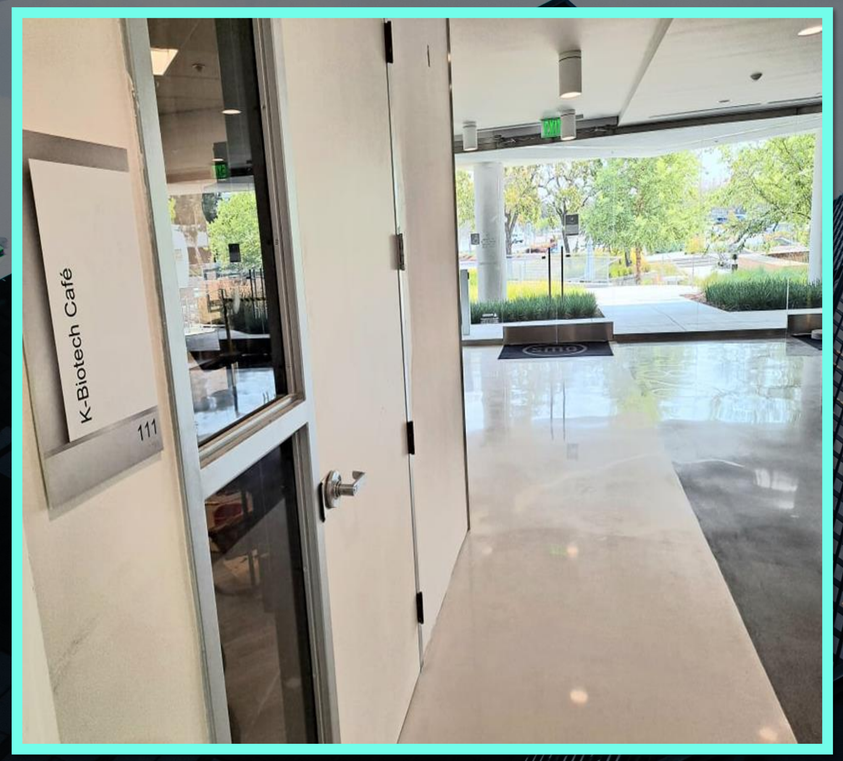
미국 인허가 및 의료기기

미국 사업에 필요한 업체에게

현지 기업 운영 경력의 실질적인 자문 제공

KBIO 미국법인 위치

케이바이오 미국 캘리포니아 법인 실리콘밸리 헬스케어 센터 사진



KBIO 실리콘밸리 바이오단지 헬스케어 센터:

Suite 111, 1820 Gateway Drive, San Mateo, California

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Profile

케이바이오솔루션

강경윤 대표이사

- 미국 공인회계사 CPA Exam 패스, 미국 인디애나 주립대 경제학사, 경영대학원 회계학석사 졸
- 2007-2014: 연매출 3조 Cook Medical 미국 인디애나주 본사 인허가 팀장
- 2014-2015: 연매출 8조 St. Jude Medical 미국 텍사스 플래노 본사 인허가 부장
  파킨슨병 치료 FDA Class III/PMA, EU Class III 미국 인허가팀 관리
- 2015-2020: 연매출 150조 Cardinal Health 미국 캘리포니아 본사 인허가 부장
  Cardinal Health의 Johnson & Johnson 2조 글로벌 사업부 M&A 진행
- 2013: 미국 FDA Regulatory Affairs Certification-RAC 취득
- 2019: 삼성서울병원 BMCC 바이오-의료 중개지원센터 자문위원 위촉
- 2020: 오송 식품의약품안전처 의료기기 허가 심사자 FDA 인허가 강연
- 2020: 서울아산병원 의료기기 임상중개 지원센터 글로벌 미국 임상전략 강의

Profile 강경윤 대표이사

미국 인디애나주 Bloomington 본사:
Cook Medical 인허가 팀장 역임

미국 텍사스 Plano 본사:
St. Jude Medical: FDA 인허가 부장 역임

Profile 강경윤 대표이사

MTN
머니투데이방송

머니투데이 TV 비즈왕 프로그램에 FDA 전문 이력 소개

Profile 강경윤 대표 KIMES 2022. 3월 코엑스 전시장 MDR 인증 전략 세미나 강연진행

Introducing 케이바이오 매니저 소개

이호정 매니저

케이바이오 서울 매니저

- **임상시험 관리, 인허가 관리 매니저**
- Colubris MX Korea: 수술용 로봇 의료기기 다국적사 한국 오피스 실장업무 (2021-2022)
- Illrorae 한국지사 경영실장 (2018-2019)
- 국제대학원 (ACTS International Graduate School) 기획처 관리자 (2016-2017)
- 노르웨이 한국대사관 Korean School 행정대표 (2015-2016)
- 노르웨이 University of Oslo: 현상분석학 Master과정
- YUST 연변과학기술대학교 총장 공로상 수상

Introducing 케이바이오 매니저 소개

Mikael Hellstrand

케이바이오 서울 매니저

- **미국/유럽 마케팅 전략**
- **한국 기업 임상 인허가 전략 지원**
- MuviK Inc. 마케팅 매니저
- 대한민국 정부초청 서강대 학부 및 석사 졸

Introducing 케이바이오 매니저 소개

안유진 과장

케이바이오 서울 매니저

- **MDR CE 인증 전문가**
- OV Medi: 인허가/품질관리 부장 (2019-2022)
- C2 Company: 의료기기 CE, FDA, 식약처 인허가 컨설팅 회사 매니저 (2018-2019)
- Genoss: 심혈관용 스텐트, 치과 임플란트 의료기기 CE, 식약처 인허가 진행 (2017-2018)
- (주)휴마시스: 체외진단 의료기기 CE, FDA, 식약처 인허가 진행 (2014-2016)
- University of California at Davis: 비임상시험소 연구원 (2012)

Introducing 케이바이오 매니저 소개

강경보 차장

케이바이오 서울 매니저

- **케이바이오 마케팅 관리**
- 지멘스 헬스케어 청각부문 세일즈 관리
- 다나허 마케팅 전략팀 과장

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전지강 사원

홍보영상/홈페이지 제작 스페셜리스트

- **의료기기/바이오 기업 전문-IR 홍보영상, 제품 유튜브 영상, 홈페이지 제작 전문가**
- JKC Production 포트폴리오 제작
- 룩앤링크사 광고 제작 경험
- 클라이언트와의 협업으로 프리랜서로 경험 보유

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Brandon Green 연구원

케이바이오 RA, 마케팅스페셜리스트

- 미국 UCLA 학부졸업
- 연세대학교 대학원
- Yonsei Graduate School of International Studies

  Master of International Finance Trade Management
- 경남국립대학교 국제교류학과 영어 교육강사

Introducing 케이바이오 매니저 소개

Melvin Dekker

케이바이오 RA, QA 채용 확정

- 네덜란드 Inholland University of Applied Sciences
- 연세대학교 국제대학원
- Yonsei Graduate School of International Studies

  Master of International Finance Trade Management
- Data Analyst: Preparing data analytical models

Introducing 케이바이오 매니저 소개

황예지 연구원

케이바이오 RA QA Staff

- 고려대학교 보건과학대학 보건환경융합과학부
- 고려대학교 생명과학대학 생명공학 이중전공
- Mexico City Elementary, Middle School High School 학부졸업

Introducing 케이바이오 매니저 소개

Inae Lee

케이바이오 USA 캘리포니아
실리콘밸리 매니저

- 미국 마케팅 전략
- 미국 Healthcare food store 비즈니스 전개

Introducing 케이바이오 USA 컨설턴트 소개

Dr. Dhanmati Rupnarine

케이바이오 USA RA, QA 매니저

- 2015-2018: Cardinal Health Senior Quality Engineer
- 2009-2015: Johnson & Johnson Cordis Senior Quality Engineer
- 2003-2009: Cordis Quality Engineer
- 2013: 미국 보스턴 National Graduate School of Quality Management-제조품질관리시스템 박사학위 수여

Introducing 케이바이오 USA 컨설턴트 소개

버나드 션
(Bernard Shen)

KBIO US Clinical, RA

- Seton Hall University: Health Professionals 리더쉽 박사과정
- 2010-2014: 의료기기 다국적사 Cook Medical 미국본사 인허가 스페셜리스트
- 2014-2016: 의료기기 다국적사 Cook Medical 미국본사 Project Manager
- 2016-2017: 의료기기 다국적사 Stryker 인허가 시니어 컨설턴트
- 2017-2019: Integra Life Sciences 인허가 부장

Introducing 케이바이오 매니저 소개

Inae Lee

케이바이오 USA 캘리포니아
실리콘밸리 매니저

- 미국 마케팅 전략
- 미국 Healthcare food store 비즈니스 전개

Introducing 케이바이오 매니저 소개

Malsoon Park

케이바이오 USA 캘리포니아
실리콘밸리 매니저

- 미국 마케팅
- 한양대학교 컴퓨터공학 석사 졸업

케이바이오 의료기기 인허가/임상관리
전주기 컨설팅 진행 서비스

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자동심장충격기 Automated External Defibrillator Class III Device MDR CE 완료

2022.10.18일자 글로벌경제 보도기사:

G글로벌경제신문
UPDATED : 2022-10-19 09:10 (수) 로그인 | 회원가입

케이바이오솔루션 ,국내 최초 유럽3등급 메디아나 AED EU MDR CE 인증 달성

이재승 의학전문기자 / 바이오 의·공학 박사 | 입력 2022.10.18 19:14
댓글 0

출처= 케이바이오솔루션

EU MDR 컨설팅 기업 케이바이오솔루션 (KBIO Solutions)은 최근 메디아나가 자동심장충격기(AED) A16제품에 대해 유럽 인증기관 EU MDR (Medical Device Regulation 2017/745) CE 인증의 3등급 제품으로 국내 최초로 케이바이오솔루션의 MDR 컨설팅 프로그램을 통해 획득했다고 18일 밝혔다.

MDR 3등급 인증은 케이바이오솔루션과 메디아나AED 2022년 1월 MDR 프로젝트 계약으로 진행되었으며, 케이바이오솔루션이 MDR인증기관의 보완요청 답변내용을 준비하는 역할을 맡았다.

많이 본 뉴스

케이바이오가 CRO로써 임상프로토콜 작성부터
임상 최종 완료부터 FDA 510(k) 허가 달성까지
5년간 진행한 프로젝트

2022.12.13일자 보도기사

한국의료기기산업협회:
케이바이오
“MDR FDA인허가 끝까지 책임진다”

의료기기뉴스라인
KMDIA 한국의료기기산업협회

“FDA 인허가·MDR CE 인증, 끝까지 책임진다”

의료기기뉴스라인 | 입력 2022.12.13 14:06 | 댓글 0

14년 RA경력 바탕으로 고객 맞춤 전문 컨설팅 서비스 제공

“FDA 인허가·MDR CE 인증, 끝까지 책임진다”

강경윤 케이바이오솔루션 대표

"국내외 의료기기 임상시험과 해외 인허가·인증 획득을 직접 끝까지 책임지고 지원하겠다." CRO이자 미국 FDA 인허가·유럽 MDR CE 인증 컨설팅을 제공하는 케이바이오솔루션 강경윤 대표는 국내 의료기기업체들의 성공적인 해외시장 진출을 견인하는 '무한 책임론'을 강조했다.

지난 2016년 9월 설립된 케이바이오솔루션은 그간 60곳에 달하는 의료기기업체의 FDA 510k, MDR CE 인증, 식품의약품안전처 확증임상시험계획·임상시험계획 승인을 성공적으로 이끌었다. 케이바이오솔루션과 여타 컨설팅 업체와의 두드러진 차이점은 무엇보다 대표이사 이력과 조직 구성에 있다. 강 대표는 14년간 다국적기업 쿡메디칼·세인트쥬드메디칼·카디널 헬스에서 RA팀 부서장을 맡아 5~6명의 팀원을 관리하며 실무 역량을 인정받았다.

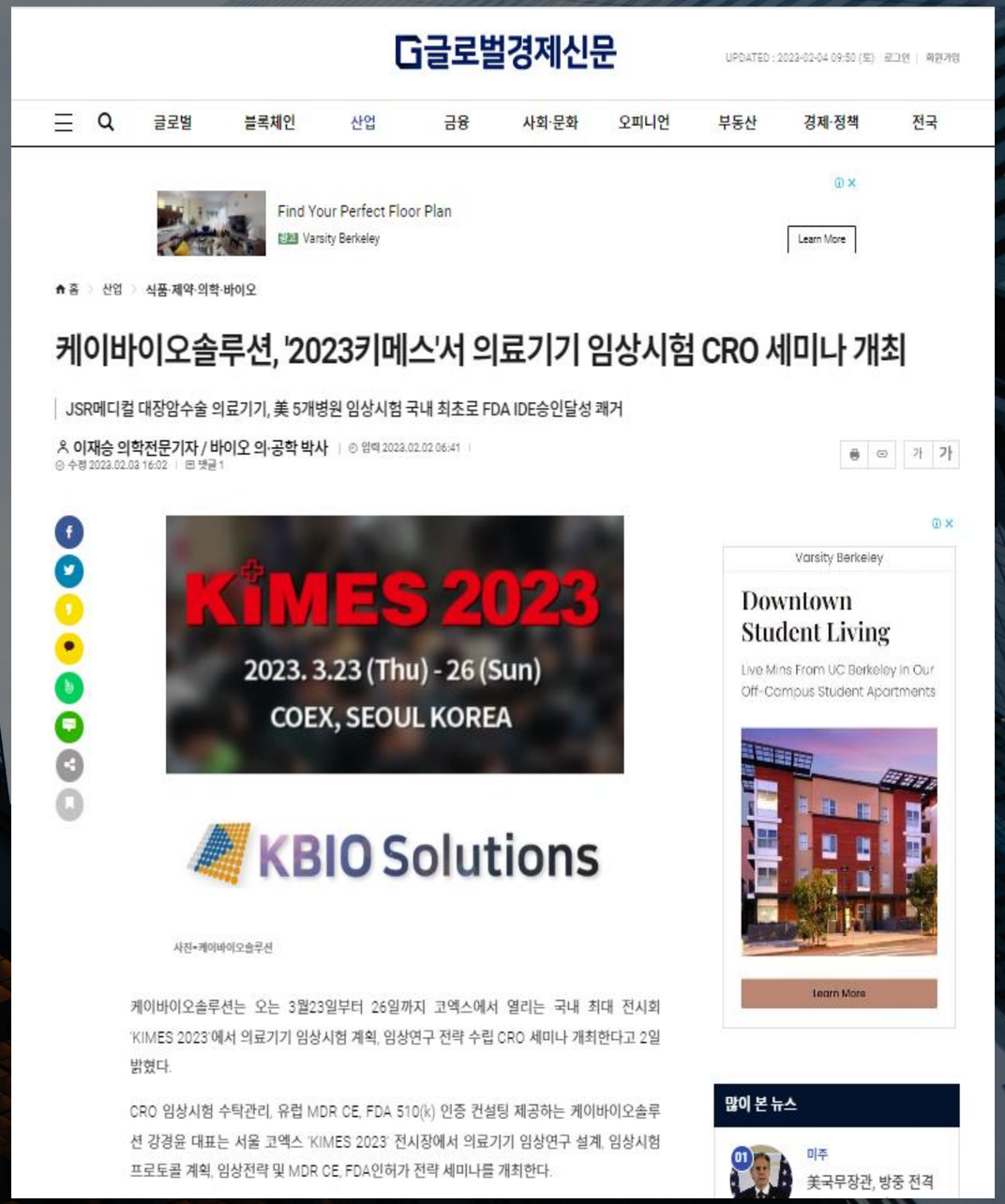
케이바이오솔루션 관련 기사 보도

키메스 2023 코엑스 전시회 세미나 개최

케이바이오가 CRO로써 키메스 2023 코엑스 전시회에서 세미나 개최

2022.02.02일자 보도기사

케이바이오솔루션:
2023 키메스
“의료기기 임상시험, MDR FDA,
1일 세미나 개최한다”



글로벌경제신문

UPDATED : 2023-02-04 09:50 (토) 로그인 | 회원가입

글로벌 | 블록체인 | 산업 | 금융 | 사회·문화 | 오피니언 | 부동산 | 경제·정책 | 전국

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케이바이오솔루션, '2023키메스'서 의료기기 임상시험 CRO 세미나 개최

JSR메디컬 대장암수술 의료기기, 美 5개병원 임상시험 국내 최초로 FDA IDE승인달성 쾌거

이재승 의학전문기자 / 바이오 의·공학 박사 | 입력 2023.02.02 06:41
수정 2023.02.03 16:02 | 댓글 1

KIMES 2023
2023. 3.23 (Thu) - 26 (Sun)
COEX, SEOUL KOREA

KBIO Solutions

사진=케이바이오솔루션

케이바이오솔루션는 오는 3월23일부터 26일까지 코엑스에서 열리는 국내 최대 전시회 'KIMES 2023'에서 의료기기 임상시험 계획, 임상연구 전략 수립 CRO 세미나 개최한다고 2일 밝혔다.

CRO 임상시험 수탁관리, 유럽 MDR CE, FDA 510(k) 인증 컨설팅 제공하는 케이바이오솔루션 강경윤 대표는 서울 코엑스 'KIMES 2023' 전시장에서 의료기기 임상연구 설계, 임상시험 프로토콜 계획, 임상전략 및 MDR CE, FDA인허가 전략 세미나를 개최한다.

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많이 본 뉴스
01 미주
美국무장관, 방중 전격

케이바이오솔루션 관련 기사 보도

케이바이오가 CRO로써 임상프로토콜 작성부터
국내 3개병원 IRB승인, 임상개시, 모니터링,
임상최종 완료부터 FDA 510(k) 허가 달성까지
5년간 진행한 프로젝트

2022.09.27일자 글로벌 경제 보도기사

케이바이오솔루션:
넥스트바이오메디컬 내시경용 상부위장관
지혈재 대규모 340명 임상성공
가천길병원, 인하대병원, 순천향병원
프로토콜 설계부터 IRB임상승인, 모니터링,
통계분석, 결과보고서 작성까지
임상시험 성공적 종료 달성

글로벌경제신문

UPDATED : 2022-10-21 20:50 (금) 로그인 | 회원가입

글로벌 블록체인 산업 금융 사회·문화 오피니언 부동산 경제·정책 전국

홈 > 산업 > 식품·제약·의학·바이오

CRO 케이바이오솔루션, 5년 노력끝에 내시경 지혈재 FDA 승인달성 쾌거

이재승 의학전문기자 / 바이오 의·공학 박사 | 입력 2022.09.27 10:53

댓글 0

KBIO Solutions

CRO 기업 케이바이오솔루션 (KBIO Solutions, 강경윤 대표)은 최근 넥스트바이오메디컬의 내시경용 지혈재 제품, 넥스파우더 (Nexpowder)의 미국 FDA 승인을 케이바이오솔루션의 FDA 인허가 프로그램을 통해 취득했다고 27일 밝혔다.

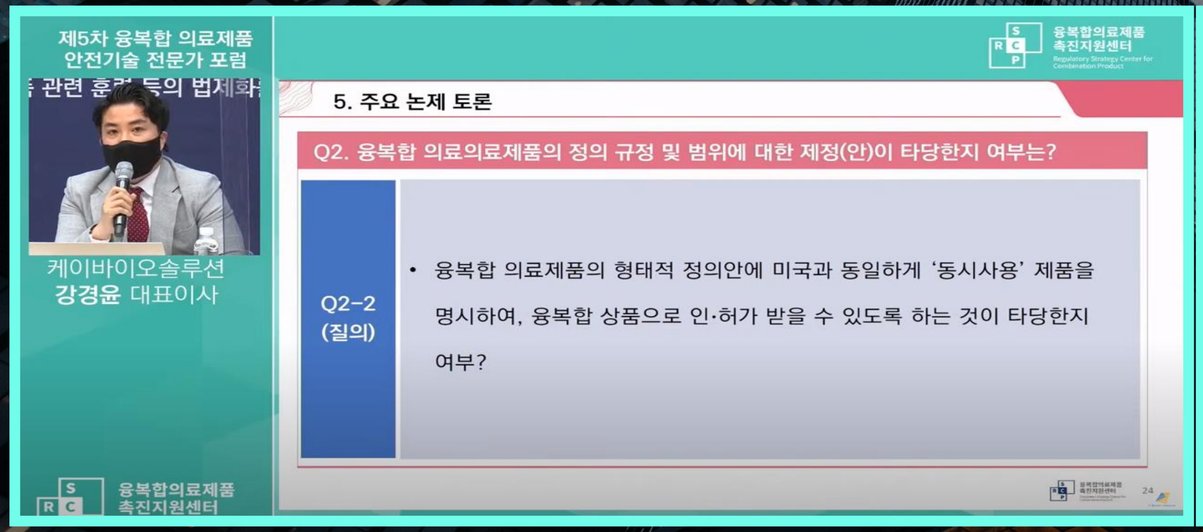
넥스파우더 FDA 인증은 케이바이오솔루션과 넥스트바이오메디컬이 2018년 1월 FDA 인허가 프로젝트 계약으로 시작되었으며, 케이바이오솔루션이 2020년 9월에 FDA 510(k) 심사접수를 수행했다.

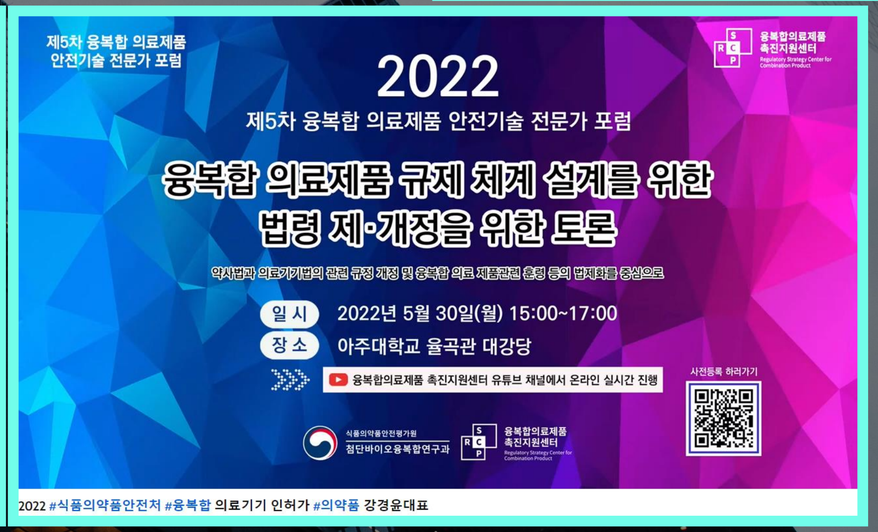
의료기기 인허가 심사에서 엄격한 510(k) 요건을 요구하는 미국 FDA 보완요청의 효과적인 대응을 위해, 케이바이오솔루션 강경윤 대표는 FDA CDRH 의료기기 심사팀과의 두차례의 Teleconference 유선 미팅을 제안하여 2020년 12월과 2021년 7월에 직접 이끌었으며, FDA와 직접 심사 교신하는 역할을 맡아왔다.

많이 본 뉴스

KBIO Solutions

강경윤 대표가 아주대학교
융복합의료제품촉진지원센터 융복합의료제품
규제 체계 설계를 위한 자문위원으로 활동





융복합 의료제품 법령 제/개정을 위한 토론 위원으로 참여

융복합의료제품 심사 가이드라인 논의

KBIO Solutions

케이바이오솔루션: 식약처 신약 임상시험 IND 승인달성
MSA 다계통위축증 PET CT 분석 임상시험

서울경제

증권 부동산 경제·금융 산업 정치 사회 국제 오피니언 문화·스포츠

지수정보 종목정보 국내증시 공시 종목·투자전략 정책 해외증시 채권 재테크 IB&Deal 증권정보 증권일반 News봇

증권 › 종목·투자전략

[SEN]카이노스메드, 다계통위축증 치료제…임상2상 IND 식약처 '승인'

입력 2021-10-25 08:21:02 수정 2021.10.25 08:21:02 배요한 기자

뉴스듣기 가

[서울경제TV=배요한기자] 카이노스메드(284620)는 25일 희귀 퇴행성 뇌질환(CNS)인 다계통위축증(MSA) 치료제 후보물질(KM-819)의 임상 2상 임상시험계획(IND)을 식품의 약품안전처로부터 승인 받았다고 밝혔다.

카이노스메드는 그동안 세포 및 동물모델에서 우수한 효능과 임상 1상에서 높은 안전성을 보인 KM-819를 임상2상에 진입시키게 됐다. 임상2상은 실제 환자를 대상으로 한 시험으로 약효의 평가가 주 목적인 개념입증(POC , Proof-of-concept) 시험이다.

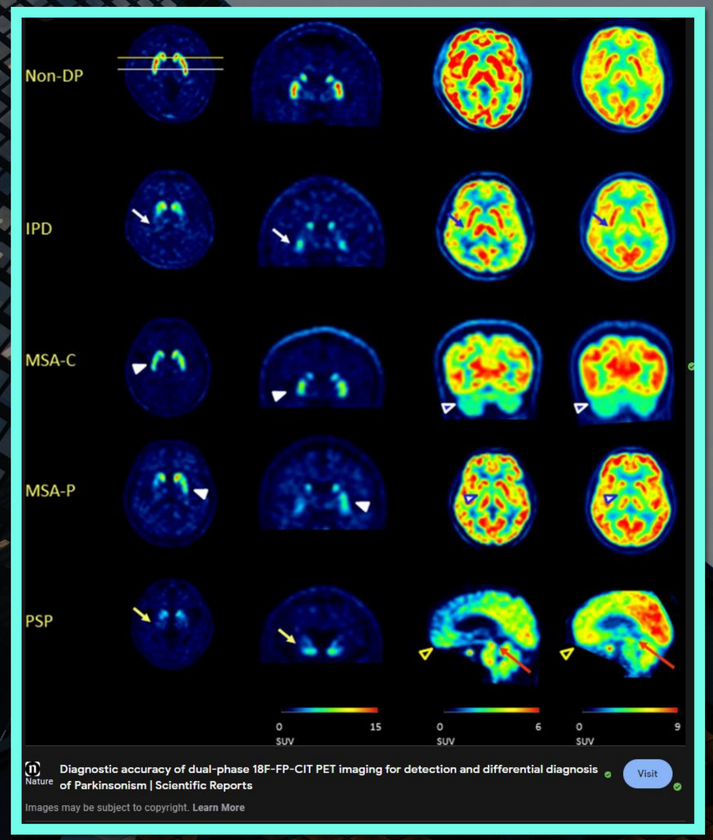
다계통위축증은 파킨슨병과 유사한 운동장애 질환이다. 하지만 파킨슨병과 달리 뚜렷한 증상완화제가 없어서 증상치료도 어렵고, 더군다나 진전이 매우 빨라서 수명이 크게 단축되는 치명적 질환이다. 치료제 개발이 매우 절실한 실정이다.

이 질환은 뇌의 일부에서 뇌세포사멸로 인한 기능상실이 운동장애로 나타나며, 시간에 따라 증세가 중증으로 진행되어 6-10년 정도 생존하는데 그친다. 그동안 많은 글로벌 제약회사가 다계통위축증 치료제 개발에 노력했으나 아직 성공하지 못했다. 일부는 현재 임상 중에 있다. 카이노스메드의 KM-819는 타깃과 약물기전이 다른 회사와는 전혀 다르고, 성공 시 그 효과가 역시 더 클 수 있다는 장점을 가지고 있다.

KM-819는 카이노스메드가 현재 파킨슨병 치료제로 개발하고 있으며 최근 미국에서 임상2상 IND를 FDA에 신청한 약물이다. KM-819는 질환의 진전3을 정지 혹은 감소시키는 질병조절치료제(disease-modifying drug)로써, 증상완화제가 아닌 근본적 치료제이다. KM-819는 세포의 죽음을 촉진하는 FAF1이라는 단백질의 저해제로서 First-in-Class 신약 후보물질이다. KM-819는 신경세포를 보호하고 사멸을 저해하며, 자가포식(autophagy) 기능을 활성화해 알파시누클레인(alpha-synuclein)의 분해를 촉진하여 축적을 억제하는 효과를 가진다.

오늘의 핫토픽

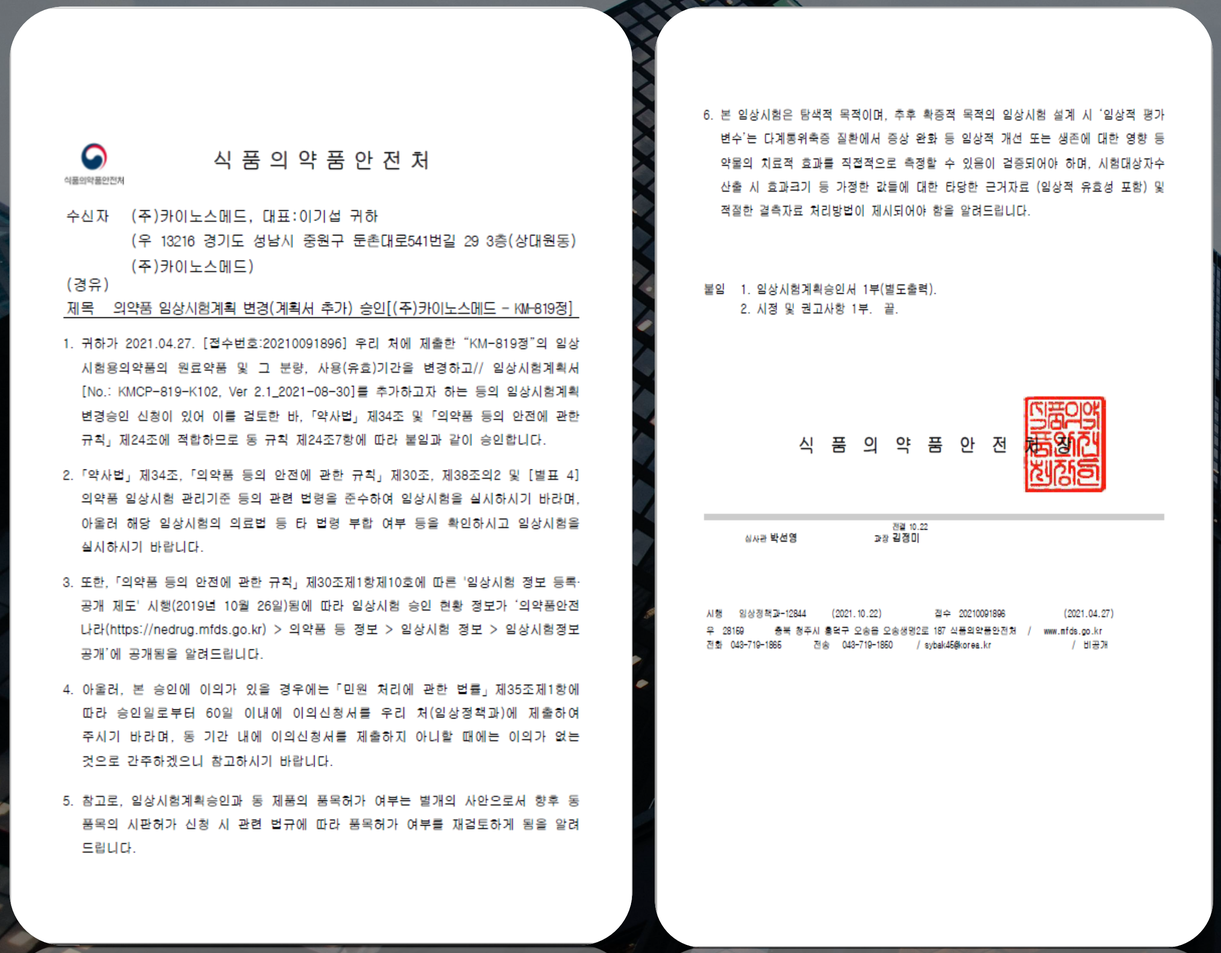
고물가 경고음 높인 한은
이재용 광폭 행보
인천공항 24시간 체제로
건설은행 세운다
"차라리 월세가 낫다"



케이바이오솔루션에서
상장사 카이노스메드
제약사의 다계통위축증
MSA 2상 PET CT분석
임상시험 식약처 및 아산병원
IRB 승인을 취득했습니다.

KBIO Solutions

케이바이오솔루션이 코스닥 상장사 (주)카이노스메드 신약 2상 IND승인 달성



식품의약품안전처

식 품 의 약 품 안 전 처

수신자 (주)카이노스메드, 대표:이기섭 귀하
(우 13216 경기도 성남시 중원구 둔촌대로541번길 29 3층(상대원동)
(주)카이노스메드)

(경유)

제목 의약품 임상시험계획 변경(계획서 추가) 승인[(주)카이노스메드 - KM-819정]

1. 귀하가 2021.04.27. [접수번호:20210091896] 우리 처에 제출한 "KM-819정"의 임상시험용의약품의 원료약품 및 그 분량, 사용(유효)기간을 변경하고// 임상시험계획서 [No.: KMCP-819-K102, Ver 2.1_2021-08-30]를 추가하고자 하는 등의 임상시험계획 변경승인 신청이 있어 이를 검토한 바, 「약사법」 제34조 및 「의약품 등의 안전에 관한 규칙」 제24조에 적합하므로 동 규칙 제24조7항에 따라 붙임과 같이 승인합니다.

2. 「약사법」 제34조, 「의약품 등의 안전에 관한 규칙」 제30조, 제38조의2 및 [별표 4] 의약품 임상시험 관리기준 등의 관련 법령을 준수하여 임상시험을 실시하시기 바라며, 아울러 해당 임상시험의 의료법 등 타 법령 부합 여부 등을 확인하시고 임상시험을 실시하시기 바랍니다.

3. 또한, 「의약품 등의 안전에 관한 규칙」 제30조제1항제10호에 따른 '임상시험 정보 등록·공개 제도' 시행(2019년 10월 26일)됨에 따라 임상시험 승인 현황 정보가 '의약품안전나라(https://nedrug.mfds.go.kr) > 의약품 등 정보 > 임상시험 정보 > 임상시험정보 공개'에 공개됨을 알려드립니다.

4. 아울러, 본 승인에 이의가 있을 경우에는 「민원 처리에 관한 법률」 제35조제1항에 따라 승인일로부터 60일 이내에 이의신청서를 우리 처(임상정책과)에 제출하여 주시기 바라며, 동 기간 내에 이의신청서를 제출하지 아니할 때에는 이의가 없는 것으로 간주하겠으니 참고하시기 바랍니다.

5. 참고로, 임상시험계획승인과 동 제품의 품목허가 여부는 별개의 사안으로서 향후 동 품목의 시판허가 신청 시 관련 법규에 따라 품목허가 여부를 재검토하게 됨을 알려드립니다.

6. 본 임상시험은 탐색적 목적이며, 추후 확증적 목적의 임상시험 설계 시 '임상적 평가변수'는 다계통위축증 질환에서 증상 완화 등 임상적 개선 또는 생존에 대한 영향 등 약물의 치료적 효과를 직접적으로 측정할 수 있음이 검증되어야 하며, 시험대상자수 산출 시 효과크기 등 가정한 값들에 대한 타당한 근거자료 (임상적 유효성 포함) 및 적절한 결측자료 처리방법이 제시되어야 함을 알려드립니다.

붙임 1. 임상시험계획승인서 1부(별도출력).
2. 시정 및 권고사항 1부. 끝.

식 품 의 약 품 안 전 처 장

검열 10.22
심사관 박선영 과장 임정미

시행 임상정책과-12844 (2021.10.22) 접수 20210091896 (2021.04.27)
우 28169 충북 청주시 흥덕구 오송읍 오송생명2로 187 식품의약품안전처 / www.mfds.go.kr
전화 043-719-1866 전송 043-719-1860 / sybak45@korea.kr / 비공개

KBIO PET 임상 업력:
식약처 임상시험 IDE 승인 받은 MSA 다계통위축증 PET CT분석 임상시험

2021년 10월

신약 2상 식품의약품안전처
임상시험계획승인
IND 취득

KBIO Solutions

케이바이오가 CRO로써 대장암수술 임상프로토콜 FDA와 3번의 Pre-Submission 미팅을 진행하여 FDA 임상승인 (IDE conditional approval)까지 달성한 프로젝트

2023.01.30일자 보도기사

"케이바이오솔루션:
대장암절제수술 인공장관 의료기기
미국 뉴욕주립대등 5개병원
256명 대규모 확증임상
FDA IDE 임상승인달성"

글로벌경제신문

UPDATED : 2023-02-04 09:40 (토) 로그인 | 회원가입

글로벌 | 블록체인 | 산업 | 금융 | 사회·문화 | 오피니언 | 부동산 | 경제·정책 | 전국

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케이바이오솔루션, 美 5개병원 임상시험 국내 최초로 FDA IDE승인달성 쾌거

KBIO "JSR메디컬 대장암수술 의료기기 대규모 256명 확증, 임상 성공 이끌겠다"

이재승 의학전문기자 / 바이오 의·공학 박사 | 입력 2023.01.30 07:59 | 수정 2023.01.30 08:03 | 댓글 0

CRO 임상시험, MDR CE, FDA 승인 진행하는 코엑스 전시회 부스에서의 케이바이오솔루션/사진=케이바이오

CRO 임상시험 수탁관리, 유럽 MDR CE, FDA 510(k) 인증 컨설팅 제공하는 케이바이오솔루션(대표 강경운) 지난 1월 26일(현지시간) 미국 식품의약품안전국 FDA로부터 미국 뉴욕주립대병원등 5개 병원에서 256명의 임상환자를 대상으로 (주)제이에스알메디컬 대장암수술 의료기기의 대규모 확증 임상시험 계획에 대한 FDA의 공식승인 (IDE)을 취득했다고 30일 밝혔다.

국내 벤처 의료기기 기술로, 가장 규모가 큰 미국 시장에서 뉴욕주의 5개 메이저 병원(뉴욕주 버팔로 병원(State University of New York (SUNY) at Buffalo Hospital), 뉴욕주 스토니 브룩 병원 (SUNY Stony Brook Hospital), 뉴욕주 업스테이트 병원 (SUNY Upstate Hospital), 마운트사이나이 병원 (Mount Sinai Hospital), 뉴욕주 병원)에서 진행할 예정이다.

많이 본 뉴스

01 미주
美국무장관, 방중 전격 취소...미-중 관계, 중국

KBIO Solutions

MDR 인증 진행 : 케이바이오 강경윤 대표 한국무역협회 의료기기 인허가 세미나 언론보도

2022.10.20일자 연합뉴스 보도기사

연합뉴스

"EU, 의료기기 인증기준 강화...정부·업계 발빠르게 대응해야"

해외 의료기기 인허가 컨설팅기업인 케이바이오솔루션의 강경윤 대표도 "새로 도입되는 EU 의료기기 인증제도는 품목 분류, 임상시험 절차, 인증기관, 의료기기 데이터베이스 등 여러 항목에서 기존보다 강화된 기준을 요구하고 있다"고 분석했다.

이어 "우리 기업들은 관련 자료를 충실히 준비하고, 최대한 빨리 인증 절차에 돌입해 인증에 소요되는 시간을 조금이라도 단축시켜야 한다"고 덧붙였다.

EU의 의료기기 시장은 인구 고령화와 정부의 적극적인 헬스케어 인프라 구축 정책으로 2028년까지 매년 5% 이상 고속 성장할 것으로 전망된다.

조빛나 무협 브뤼셀지부장은 "EU 의료기기 시장은 지속적인 성장이 예상되지만, 신규 인증 취득에 많은 비용이 드는데다 인증 절차가 복잡해 중소기업이 대응하기 어려운 부분이 있다"며 "정부와 관련 기관의 적극적인 지원이 필요하다"고 조언했다.

hee1@yna.co.kr

KBIO Solutions

존슨앤존슨 2020년부터 MDR 인증 컨설팅 제공: 2021년, 2022년 MDR CE 승인달성

미국 존슨앤존슨 캘리포니아 본사에 2020년초부터 현재까지 3차년도에 걸쳐 MDR 컨설팅 제공하고 있습니다.

존슨앤존슨 총 7개품목 MDR 심사파일준비

2021년도 MDR CE 승인취득

안구건조증 치료 LipiFlow:

하드웨어+소프트웨어 디바이스 MDR CE 승인획득 비롯하여

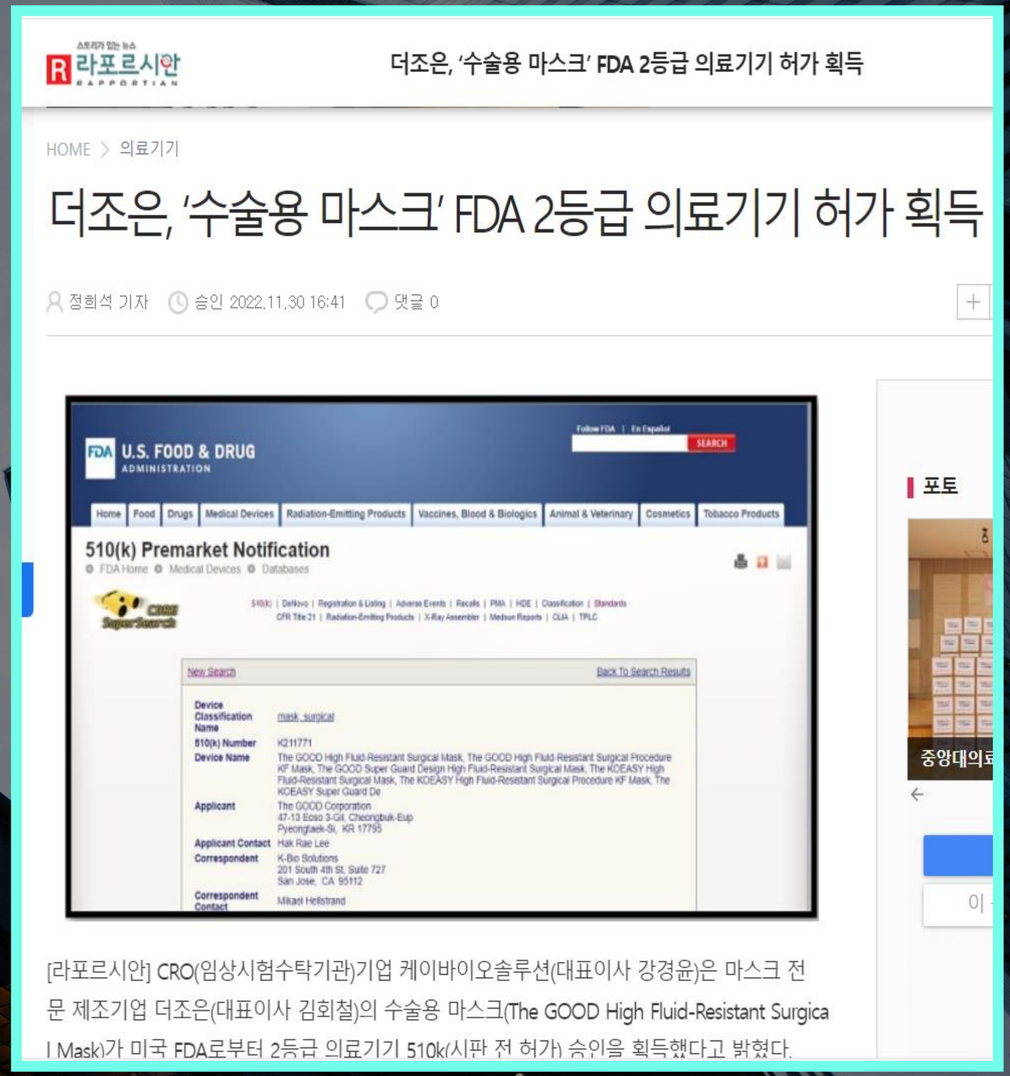
2020년부터 존슨앤존슨 총 7개 품목의 MDR Submission File을 준비해온 축척된 MDR 경험을 바탕으로 컨설팅 제공

KBIO Solutions

케이바이오솔루션 관련 기사 보도

2022.11.30일자 라포르시안 보도기사

케이바이오가 국내최초로 수술용마스크 FDA 510(k) 승인달성



라포르시안

더조은, '수술용 마스크' FDA 2등급 의료기기 허가 획득

HOME > 의료기기

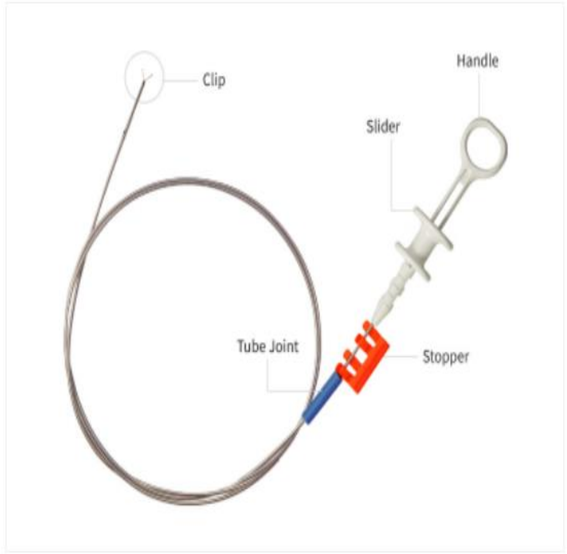
더조은, '수술용 마스크' FDA 2등급 의료기기 허가 획득

정희석 기자 승인 2022.11.30 16:41 댓글 0

[라포르시안] CRO(임상시험수탁기관)기업 케이바이오솔루션(대표이사 강경윤)은 마스크 전문 제조기업 더조은(대표이사 김회철)의 수술용 마스크(The GOOD High Fluid-Resistant Surgical Mask)가 미국 FDA로부터 2등급 의료기기 510k(시판 전 허가) 승인을 획득했다고 밝혔다.

KBIO Solutions

(주)파인메딕스 ClearEndoclip 내시경용 지혈클립 의료기기 첫번째 제품 2020년 FDA 510(k) 승인 취득하였습니다.



일회용 ClearEndoclip은 출혈 병변에 정확한 지혈을 제공. 또한 병변에 클립을 쉽게 타겟팅하고 배치 할 수 있는 회전 기능 탑재.

제품 특징

- 핸들을 1:1 비율로 회전 (한 손으로 튜브 조인트를 잡고 핸들 회전)
- 병변에 클립 체결 전 Re-open 가능 (주의 : 최대5회 까지 Re-open 가능)
- MR 조건부 승인
- 클립 벌림폭: 11mm

510(k) Premarket Notification

FDA Home | Medical Devices | Databases

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search | Back To Search Results

Device Classification Name	Hemostatic Metal Clip For The Gi Tract
510(K) Number	K183021
Device Name	ClearEndoclip
Applicant	Finemedix Co., Ltd. 60, Maeyeo-Ro, Dong-Gu Daegu, KR 41065
Applicant Contact	Heon-Sik Lee
Correspondent	K-Biotech Inc. 589 Oakwood Drive Santa Clara, CA 95054
Correspondent Contact	Kyungyoon Kang
Regulation Number	876.4400
Classification Product Code	PKL
Subsequent Product Codes	FHN MND
Date Received	11/01/2018
Decision Date	06/28/2019
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Gastroenterology/Urology
510k Review Panel	Gastroenterology/Urology
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

2019, 6월 **내시경용클립 FDA 510k 승인**

KBIO Solutions

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케이바이오가 코스닥 상장사 (주)리메드 ALTMS 제품 우울증 치료용 경두개 자기 자극기 2021년 11월 FDA 510(k) 승인취득

U.S. FOOD & DRUG ADMINISTRATION

November 26, 2021

REMED Co., Ltd
Kyungyoon Kang
CEO
K-Biotech
201 South 4th Street, Suite 727
San Jose, California 95112

Re: K202537
Trade/Device Name: ALTMS Magnetic Stimulation Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulation system
Regulatory Class: Class II
Product Code: OBP
Dated: October 20, 2021
Received: October 28, 2021

ear Kyungyoon Kang:

e have reviewed your Section 510(k) premarket notification of intent to market the device referenced ove and have determined the device is substantially equivalent (for the indications for use stated in the closure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the actment date of the Medical Device Amendments, or to devices that have been reclassified in accordance th the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a emarket approval application (PMA). You may, therefore, market the device, subject to the general ntrols provisions of the Act. Although this letter refers to your product as a device, please be aware that me cleared products may instead be combination products. The 510(k) Premarket Notification Database cated at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination oduct submissions. The general controls provisions of the Act include requirements for annual registration, ting of devices, good manufacturing practice, labeling, and prohibitions against misbranding and ulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We mind you, however, that device labeling must be truthful and not misleading.

KBIO Solutions

케이바이오가 코스닥 상장사
(주)리메드 Talent Pro
Electromagnetic Stimulation
자기장 만성통증 치료기기 제품
2021년 5월 FDA 510k 승인취득

510(k) Premarket Notification

FDA Home ◦ Medical Devices ◦ Databases

CDRH SuperSearch

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search | Back To Search Results

Device Classification Name	Stimulator, Muscle, Powered
510(K) Number	K202031
Device Name	Talent-Pro Electromagnetic Stimulator
Applicant	Remed Co., Ltd #301-#303 Migun Techno World II, 187, Techno 2-Ro Yuseong-Gu Daejeon, KR 34025
Applicant Contact	Yoonsoo Nam
Correspondent	K-Biotech 201 South 4th Street, Suite 727 San Jose, CA 95112
Correspondent Contact	Kyungyoon Kang
Regulation Number	890.5850
Classification Product Code	IPF
Date Received	07/22/2020
Decision Date	05/06/2021
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Physical Medicine
510k Review Panel	Physical Medicine
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

KBIO Solutions

케이바이오가 (주)마이크로엔엑스 FDA 510(k) 승인취득

510(k) Premarket Notification

FDA Home ▸ Medical Devices ▸ Databases

CDRH SuperSearch

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search — Back To Search Results

Device Classification Name	Handpiece, Belt And/Or Gear Driven, Dental
510(K) Number	K192809
Device Name	Dental Handpiece
Applicant	Micro-NX Co., Ltd. 22 Maeyeo-Ro 1 Gil, Dong Gu Daegu, KR 41059
Applicant Contact	Sojeong Park
Correspondent	K-Bio Solutions 589 Oakwood Drive Santa Clara, CA 95054
Correspondent Contact	Kyungyoon Kang
Regulation Number	872.4200
Classification Product Code	EFA
Date Received	10/01/2019
Decision Date	08/25/2020
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Dental
510k Review Panel	Dental
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

2020.10월 **FDA Dental Handpick 510k 승인**

KBIO Solutions

케이바이오가 (주)마이크로엔엑스 FDA 510(k) 승인취득

510(k) Premarket Notification

FDA Home ▸ Medical Devices ▸ Databases

CDRH SuperSearch

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search — Back To Search Results

Device Classification Name	handpiece, belt and/or gear driven, dental
510(k) Number	K220577
Device Name	Dental Handpiece, Model CA160, CA160L, and CA500L
Applicant	Micro-NX Co., Ltd. 22 Maeyeo-Ro 1 Gil Dong-Gu, KR 41059
Applicant Contact	Sojeong Park
Correspondent	K-Bio Solutions 201 South 4th Street, Suite 727 San Jose, CA 95112
Correspondent Contact	Seohee Kwon
Regulation Number	872.4200
Classification Product Code	EFA
Date Received	02/28/2022
Decision Date	07/29/2022
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Dental
510k Review Panel	Dental
Summary	Summary
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

2022.7월 **FDA Dental Handpiece, Model CA160, CA160L, and CA500L5, FDA 510(k) 승인**

KBIO Solutions

케이바이오가 (주)더조은 FDA 510(k) 승인취득

510(k) Premarket Notification

FDA Home ◦ Medical Devices ◦ Databases

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search — Back To Search Results

Device Classification Name	mask, surgical
510(k) Number	K211771
Device Name	The GOOD High Fluid-Resistant Surgical Mask, The GOOD High Fluid-Resistant Surgical Procedure KF Mask, The GOOD Super Guard Design High Fluid-Resistant Surgical Mask, The KOEASY High Fluid-Resistant Surgical Mask, The KOEASY High Fluid-Resistant Surgical Procedure KF Mask, The KOEASY Super Guard De
Applicant	The GOOD Corporation 47-13 Eoso 3-Gil, Cheongbuk-Eup Pyeongtaek-Si, KR 17795
Applicant Contact	Hak Rae Lee
Correspondent	K-Bio Solutions 201 South 4th St, Suite 727 San Jose, CA 95112
Correspondent Contact	Mikael Hellstrand
Regulation Number	878.4040
Classification Product Code	FXX
Date Received	06/08/2021
Decision Date	08/24/2022
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General & Plastic Surgery
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

2022.8월 **수술 마스크 FDA 510(k) 승인**

KBIO Solutions

케이바이오가 (주)파인메딕스 ClearEndoclip
내시경용 지혈클립 의료기기 두번째 제품 2020년 FDA 510(k) 승인취득하였습니다.

510(k) Premarket Notification

FDA Home ● Medical Devices ● Databases

CDRH SuperSearch

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

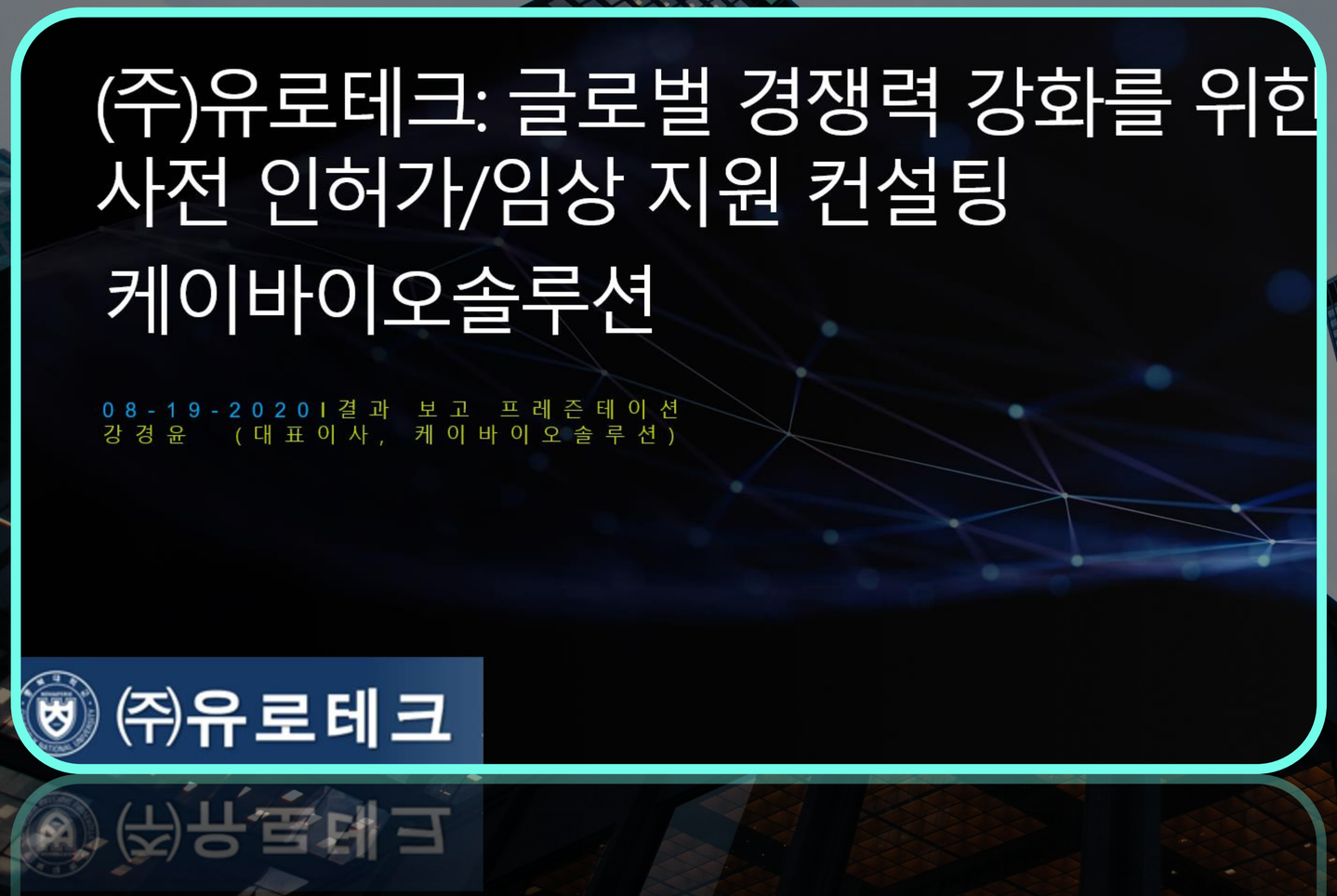
New Search | Back To Search Results

Device Classification Name	Hemostatic Metal Clip For The Gi Tract
510(K) Number	K200217
Device Name	ClearEndoclip
Applicant	Finemedix Co., Ltd. 60, Maeyeo-Ro, Dong-Gu Daegu, KR 41065
Applicant Contact	H. S. Lee
Correspondent	K-Bio Solutions 589 Oakwood Drive Santa Clara, CA 95054
Correspondent Contact	Kyungyoon Kang
Regulation Number	876.4400
Classification Product Code	PKL
Subsequent Product Codes	FHN MND
Date Received	01/28/2020
Decision Date	10/05/2020
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Gastroenterology/Urology
510k Review Panel	Gastroenterology/Urology
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

2022.10월 **내시경용클립 FDA 510(k) 승인**

KBIO Solutions

케이바이오가 방광암진단기기 FDA Pre-Submission 컨설팅 2020년 진행



(주)유로테크
IVD 방광암 체외진단 기기
FDA Pre-Submission
컨설팅 수행했던 이력

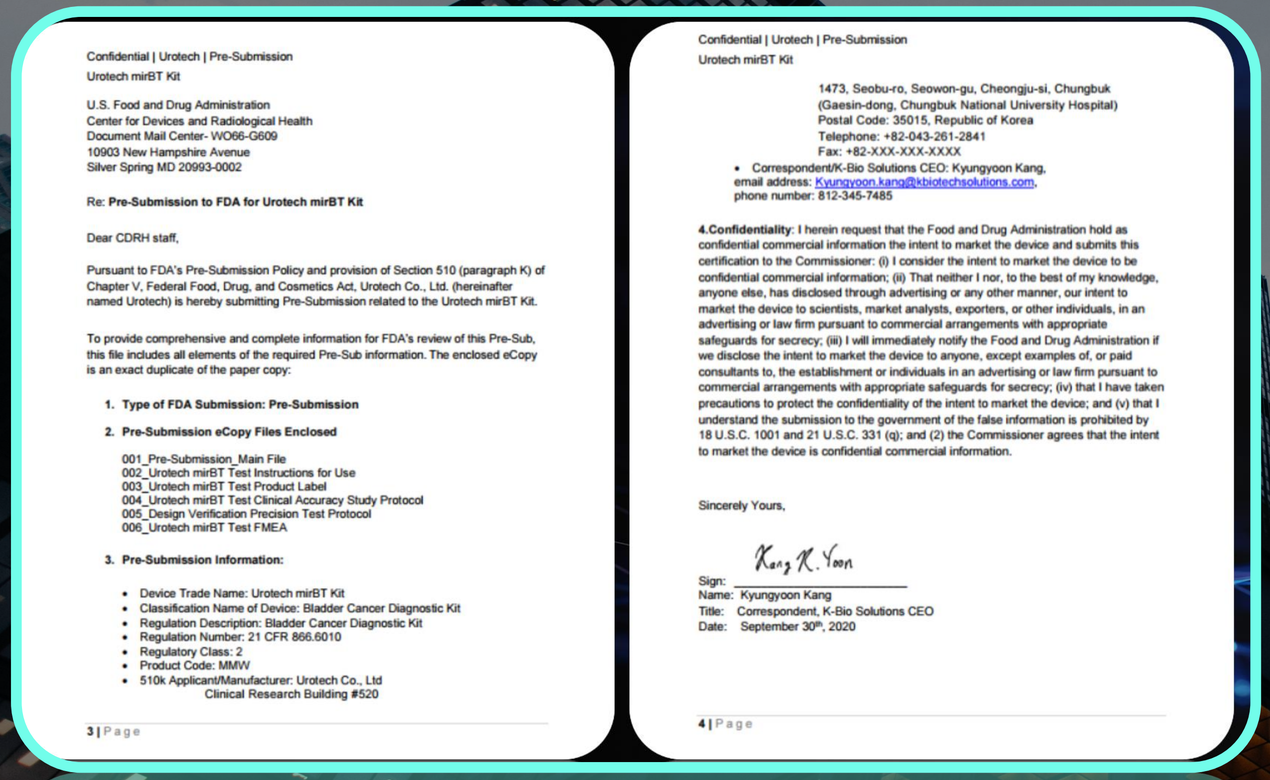
KBIO Solutions

케이바이오가 달성한 인허가 승인내역

승인/심사 번호	의료기기 승인/인증명	기술명	제조사	승인/심사
K202031	FDA 2등급 510k	자기장 물리치료 시스템 허가	(주)리메드	2021년 5월 14일 510k 승인
K192809	FDA 2등급 510k	치과 덴탈 핸드피스 기기 허가	(주)마이크로엔엑스	2020년 9월 11일 510k 승인
K201333	FDA 2등급 510k	말초혈관폐착 수술용 풍선카테터	미국 Cardinal Health	2020년 8월 25일 510k 승인
K183021	FDA 2등급 510k	소화기내과 내시경용 지혈클립 II	(주)파인메딕스	2019년 6월 28일 510k 승인
K200217	FDA 2등급 510k	소화기내과 내시경용 지혈클립 I	(주)파인메딕스	2020년 10월 5일 510k 승인
K150769	FDA 2등급 510k	정형외과 수술이식 플레이트네일	미국 Cardinal Health	2015년 12월 14일 510k 승인
BSI CE	MDR CE 인증	안구건조 치료시스템 (미국 존슨앤존슨)	미국 Johnson & Johnson	2021년 5월 MDR CE 승인
KR/01 52786	SGS ISO 13485 품목추가	가이드와이어, 인트로듀서 카테터 품목 추가	(주)성원메디칼	2018년 8월 16일 승인

KBIO Solutions

케이바이오가 방광암진단기기 FDA Pre-Submission 컨설팅 2020년 진행



Confidential | Urotech | Pre-Submission

Urotech mirBT Kit

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center- WO66-G609
10903 New Hampshire Avenue
Silver Spring MD 20993-0002

Re: **Pre-Submission to FDA for Urotech mirBT Kit**

Dear CDRH staff,

Pursuant to FDA's Pre-Submission Policy and provision of Section 510 (paragraph K) of Chapter V, Federal Food, Drug, and Cosmetics Act, Urotech Co., Ltd. (hereinafter named Urotech) is hereby submitting Pre-Submission related to the Urotech mirBT Kit.

To provide comprehensive and complete information for FDA's review of this Pre-Sub, this file includes all elements of the required Pre-Sub information. The enclosed eCopy is an exact duplicate of the paper copy:

1. **Type of FDA Submission: Pre-Submission**
2. **Pre-Submission eCopy Files Enclosed**

001_Pre-Submission_Main File
002_Urotech mirBT Test Instructions for Use
003_Urotech mirBT Test Product Label
004_Urotech mirBT Test Clinical Accuracy Study Protocol
005_Design Verification Precision Test Protocol
006_Urotech mirBT Test FMEA

3. **Pre-Submission Information:**

- Device Trade Name: Urotech mirBT Kit
- Classification Name of Device: Bladder Cancer Diagnostic Kit
- Regulation Description: Bladder Cancer Diagnostic Kit
- Regulation Number: 21 CFR 866.6010
- Regulatory Class: 2
- Product Code: MMW
- 510k Applicant/Manufacturer: Urotech Co., Ltd
  Clinical Research Building #520

3 | Page

Confidential | Urotech | Pre-Submission

Urotech mirBT Kit

1473, Seobu-ro, Seowon-gu, Cheongju-si, Chungbuk
(Gaesin-dong, Chungbuk National University Hospital)
Postal Code: 35015, Republic of Korea
Telephone: +82-043-261-2841
Fax: +82-XXX-XXX-XXXX

- Correspondent/K-Bio Solutions CEO: Kyungyoon Kang,
  email address: Kyungyoon.kang@kbiotechsolutions.com,
  phone number: 812-345-7485

4.Confidentiality: I herein request that the Food and Drug Administration hold as confidential commercial information the intent to market the device and submits this certification to the Commissioner: (i) I consider the intent to market the device to be confidential commercial information; (ii) That neither I nor, to the best of my knowledge, anyone else, has disclosed through advertising or any other manner, our intent to market the device to scientists, market analysts, exporters, or other individuals, in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy; (iii) I will immediately notify the Food and Drug Administration if we disclose the intent to market the device to anyone, except examples of, or paid consultants to, the establishment or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy; (iv) that I have taken precautions to protect the confidentiality of the intent to market the device; and (v) that I understand the submission to the government of the false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331 (q); and (2) the Commissioner agrees that the intent to market the device is confidential commercial information.

Sincerely Yours,

Sign: _____
Name: Kyungyoon Kang
Title: Correspondent, K-Bio Solutions CEO
Date: September 30th, 2020

4 | Page

(주)유로테크
IVD 방광암 체외진단기기
FDA Pre-Submission
컨설팅 수행했던 이력

KBIO Solutions

MDR 인증 컨설팅 제공

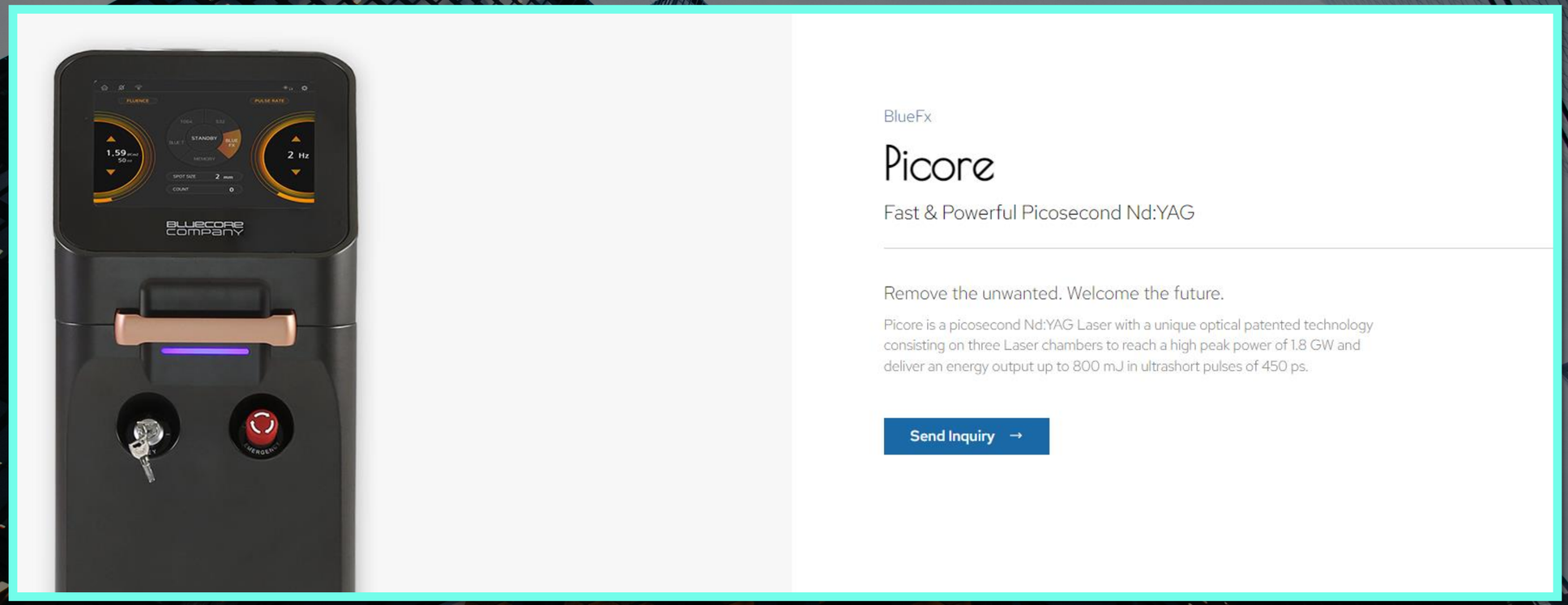
케이바이오 2022년도 MDR CE 컨설팅:
코스닥 상장사 (주)메디아나 MDR 인증 달성

자동제세동기 Automated External
Defibrillator Class III Device MDR CE 완료

KBIO Solutions

MDR 인증 컨설팅 제공

케이바이오 2022년도 MDR CE 컨설팅:
블루코어 컴퍼니



블루코어 컴퍼니 Picore Laser Class IIb Device MDR
CE 컨설팅 진행중

KBIO Solutions

MDR 인증 컨설팅 제공

케이바이오 2022년도 MDR CE 컨설팅: 대구첨복단지 (주)마이크로엔엑스 MDR 컨설팅 진행중

대구 첨단복합단지 (주)마이크로엔엑스
덴탈 핸드피스, 임플란트 엔진, 토크 드라이버,
일렉 빌트인 전기모터, 일렉 모바일 전기모터
5개 품목의 MDR CE 컨설팅 진행중

KBIO Solutions

케이바이오가 (주)메디센서 당화혈색소 HbA1c IVD FDA 510(k) 컨설팅 2019년 진행

CareU™ Analyzer 100
당화혈색소 측정기

일체형

- 측정에 필요한 모든 시약 및 샘플링 일체화 신속/정확
- 소량의 혈액 샘플(3㎕)로 빠른 검사 결과(3분) 사용자 중심
- 하나의 검사로 HbA1c and eAG 검사 결과
- HbA1c 단위 선택 (% 혹은 mmol/mol)

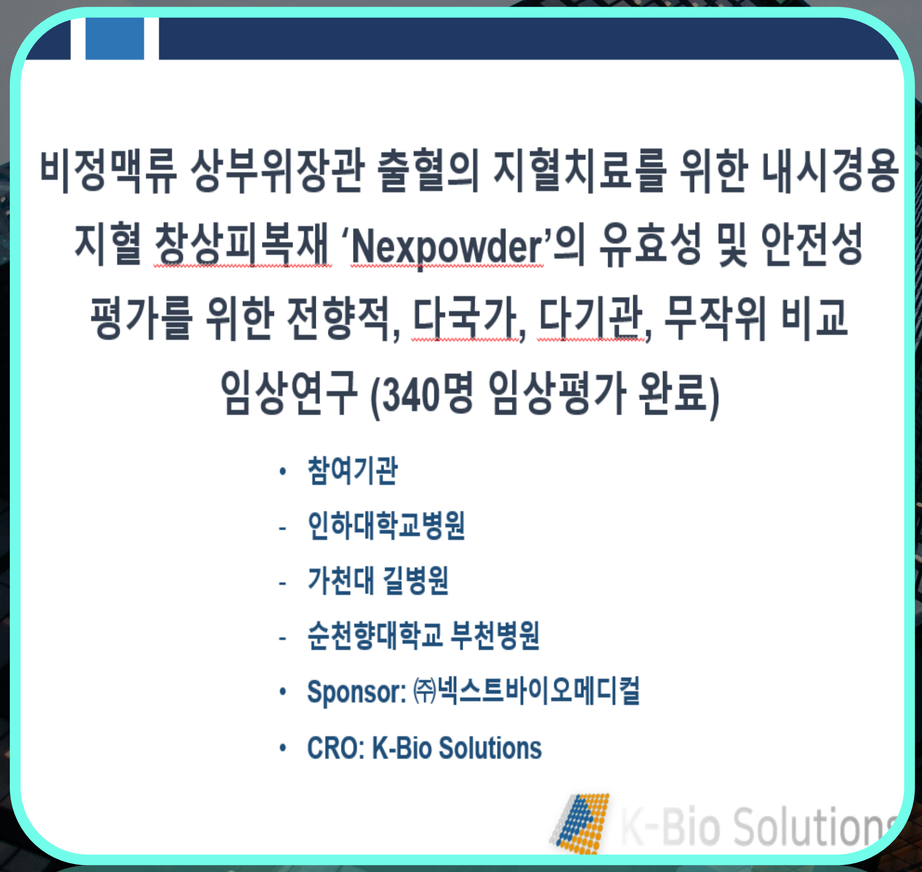
제품 설명

- 빌트인 내장 프린터
- 편리 : 풀컬러 터치스크린, 다중언어 옵션, 음성 안내 지원
- 호환성 : USB/이더넷, USB 포트를 이용한 SW 업그레이드
- 자동 lid door:
- 일체형 카트리지 : 시약, 세포막, 혈액 샘플

(주)메디센서 IVD 당화혈색소 측정기
FDA 510(k) 사전준비 컨설팅
수행했던 이력

KBIO Solutions

케이바이오가 CRO로써 임상프로토콜 작성부터
국내 3개병원 IRB승인, 임상개시, 모니터링 임상최종 완료를 이끈 프로젝트



다기관 무작위 비교 임상시험 (340명 완료)
프로토콜 설계부터 IRB임상승인, 모니터링, 통계분석,
결과보고서 작성완료

KBIO Solutions

케이바이오가 CRO로써 UCLA 임상시험관리, 임상모니터링하여

UCLA 대학 임상시험완료한 CRO 미국임상컨설팅제공

UCLA Clinical Study Commencement Meeting

Ray

UCLA School of Dentistry

SMD solutions

산업통상자원부

K-Bio Solutions

A CLINICAL TRIAL TO EVALUATE THE EFFECTIVENESS AND SAFETY OF DUAL ENERGY CONE BEAM COMPUTED TOMOGRAPHY (DE-CBCT) IMAGING FOR ASSESSMENT OF JAW BONE DENSITY.

2021 January 20th (US)

Clinical Trial Initiation Agreement is provided on slide 50.

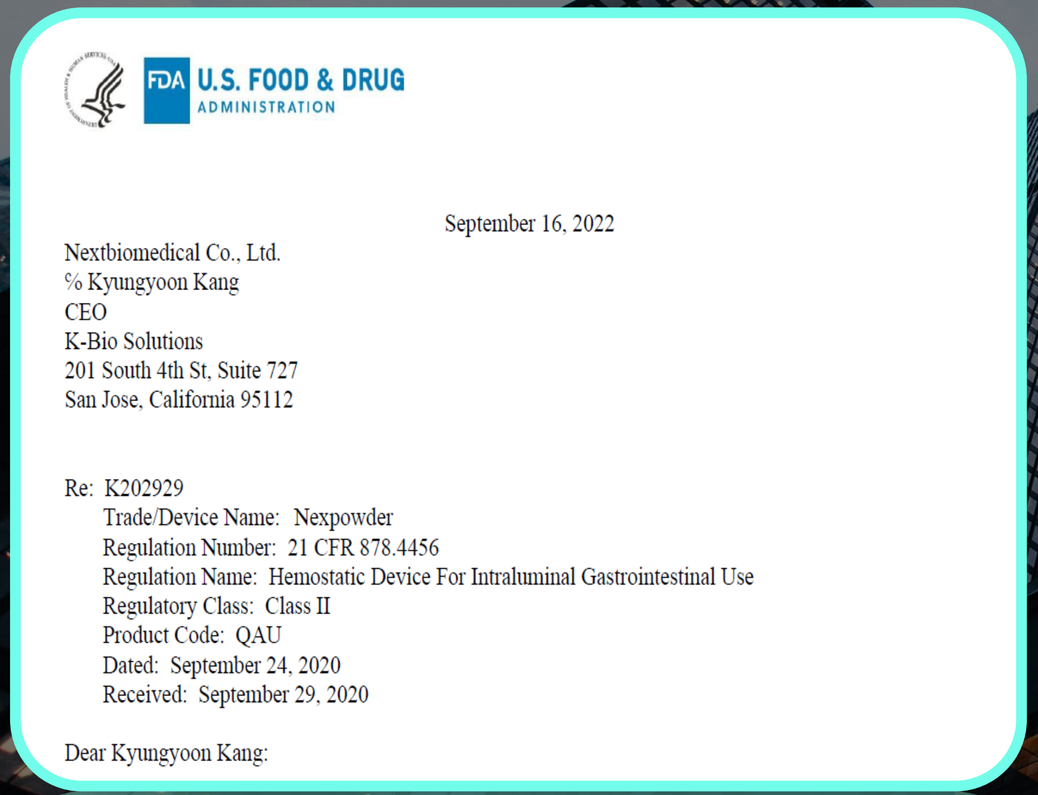
Investigational Product: Dual-energy Cone Beam Computed Tomography (DE-CBCT) Unit, RCT720
Sponsor: Ray Co., Ltd.
Funding Organization: Seoul National University
Site: UCLA Dental Center and UCLA Ronald Reagan Hospital
Principle Investigator: Sanjay M.Mallya,BDS,MDS,PhD
CRO: K-Bio Solutions & SMDsolutions
Medical Monitor: Kyungyoon Kang, CEO,MSA,RAC & Seohee Kwon CRA

미국 UCLA 대학에서 치과 골밀도측정 IVD영상진단

의료기기 미국 임상시험 완료한 이력

KBIO Solutions

2022.09.16일자에 케이바이오솔루션 FDA 510(k) Clearance
KBIO가 내시경 지혈재 FDA 510(k) 승인취득



U.S. FOOD & DRUG ADMINISTRATION

September 16, 2022

Nextbiomedical Co., Ltd.
% Kyungyoon Kang
CEO
K-Bio Solutions
201 South 4th St, Suite 727
San Jose, California 95112

Re: K202929
Trade/Device Name: Nexpowder
Regulation Number: 21 CFR 878.4456
Regulation Name: Hemostatic Device For Intraluminal Gastrointestinal Use
Regulatory Class: Class II
Product Code: QAU
Dated: September 24, 2020
Received: September 29, 2020

Dear Kyungyoon Kang:

NEXTBIOMEDICAL

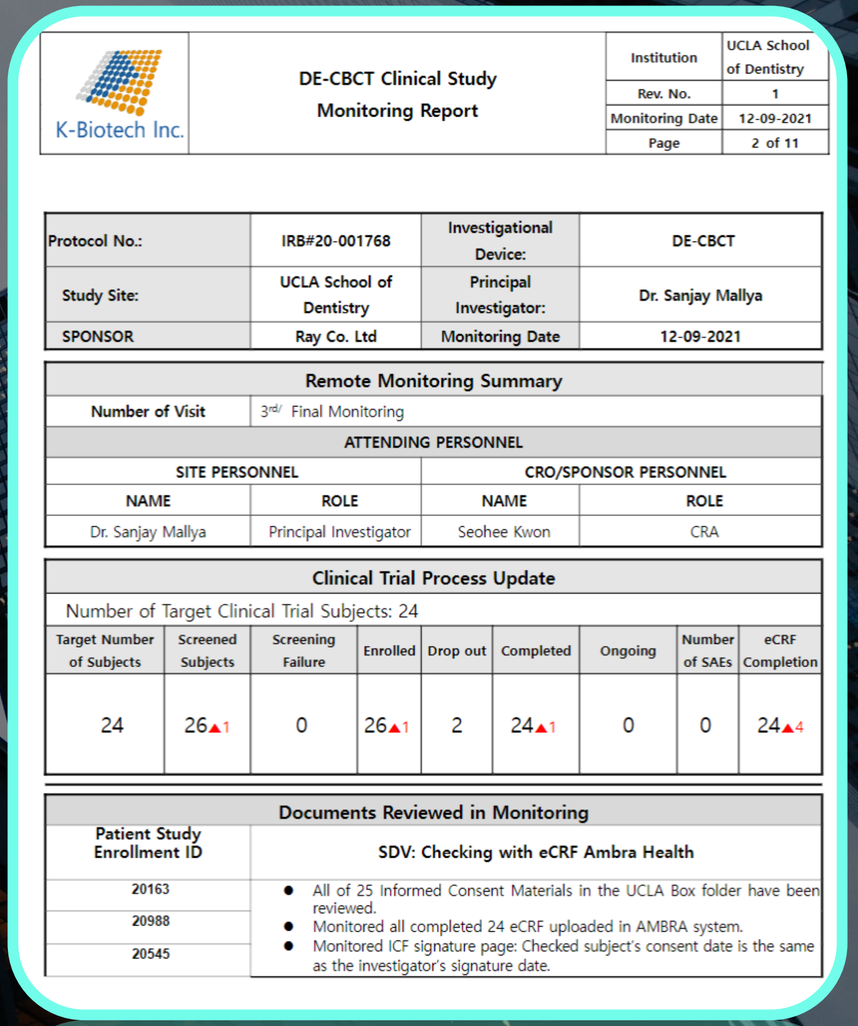
소화기내과 내시경지혈재 FDA 510(k) 승인

KBIO Solutions

케이바이오가 CRO로써 미국 UCLA 임상시험관리, 임상모니터링하여 UCLA 대학 임상시험완료한 CRO 미국임상컨설팅제공

미국 UCLA 대학에서 치과 골밀도측정

IVD영상진단 의료기기 미국 임상시험 완료한 이력



K-Biotech Inc.

DE-CBCT Clinical Study Monitoring Report

Institution	UCLA School of Dentistry
Rev. No.	1
Monitoring Date	12-09-2021
Page	2 of 11

Protocol No.:	IRB#20-001768	Investigational Device:	DE-CBCT
Study Site:	UCLA School of Dentistry	Principal Investigator:	Dr. Sanjay Mallya
SPONSOR	Ray Co. Ltd	Monitoring Date	12-09-2021

Remote Monitoring Summary

Number of Visit	3rd/ Final Monitoring

ATTENDING PERSONNEL

SITE PERSONNEL		CRO/SPONSOR PERSONNEL	
NAME	ROLE	NAME	ROLE
Dr. Sanjay Mallya	Principal Investigator	Seohee Kwon	CRA

Clinical Trial Process Update

Number of Target Clinical Trial Subjects: 24

Target Number of Subjects	Screened Subjects	Screening Failure	Enrolled	Drop out	Completed	Ongoing	Number of SAEs	eCRF Completion
24	26▲1	0	26▲1	2	24▲1	0	0	24▲4

Documents Reviewed in Monitoring

Patient Study Enrollment ID	SDV: Checking with eCRF Ambra Health
20163 20988 20545	● All of 25 Informed Consent Materials in the UCLA Box folder have been reviewed. ● Monitored all completed 24 eCRF uploaded in AMBRA system. ● Monitored ICF signature page: Checked subject's consent date is the same as the investigator's signature date.

KBIO Solutions

케이바이오가 CRO로써 미국 State University of New York at Buffalo 대장암수술의 대학교수들과 국내 개발된 의료기기로 미국임상 FDA와 Pre-Submission 진행했음

미국 뉴욕주립 대학 대장암수술 의료기기 임상시험계획을
FDA Pre-Submission 통해 FDA와
직접 미국임상계획 심사 진행했음

Subject: JSR Medical, Pre-submission Meeting Minutes for the COLO-BT™
Q-Submission Number: Q202000/S002
Time and Date: 9am EST, July 29th, Friday, 2022

FDA ATTENDEES:

- Dr. Joseph A. Nielsen – Lead Reviewer
- Dr. Glenn Bell – Division Director for the Division of Renal, Gastrointestinal, Obesity and Transplantation Devices
- Dr. April K. Marrone – Acting Assistant Director of the Obesity and Hepatobiliary Medical Devices Team
- Dr. George Gibeily – Medical Officer for FDA and a General Surgeon on this file
- Dr. Diane Cordray – Animal Study Reviewer in the Obesity and Hepatobiliary Medical Devices Team

SPONSOR ATTENDEES:

- Mr. Yoon Kang – CEO, Regulatory Affairs Consulting Firm
- Mr. Mikael Hellstrand – RA Manager, Regulatory Affairs Consulting Firm
- Dr. Jae Hwang Kim – CEO & Founder, JSR Medical Co., Ltd.
- Mr. Tae Joe Kim – Vice President, JSR Medical Co., Ltd.
- Mr. Hye Soo Moon – R&D Director, JSR Medical Co., Ltd.
- Mr. Sung Yong Park – R&D Manager, JSR Medical Co., Ltd.
- Mr. Young Man Seo – QMR, JSR Medical Co., Ltd.

CLINICIAN ATTENDEES:

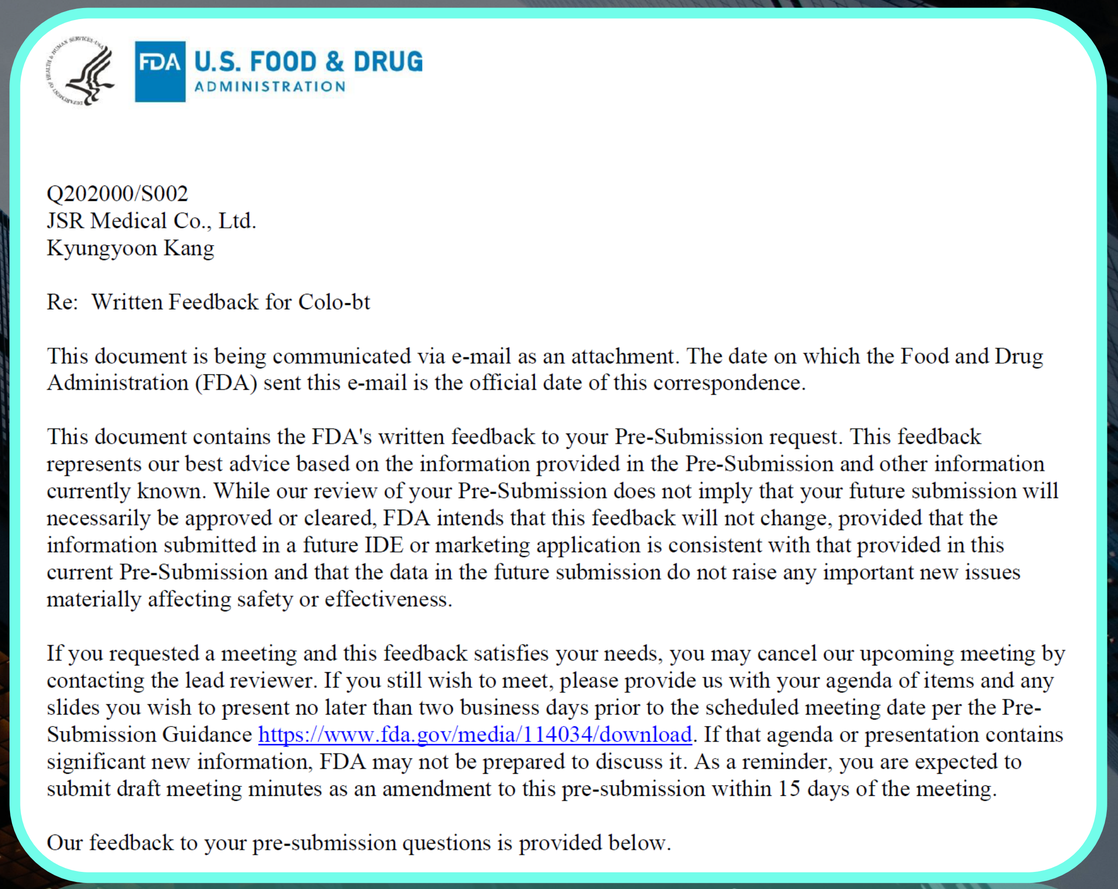
- Dr. Mark A. Falvo – Division Chief Colorectal Surgery SUNY at Buffalo, Program Director for Colorectal Fellowship SUNY at Buffalo
- Dr. Steven D. Schwaitzberg – Professor and Chair of Department of Surgery (Colon and Rectal Surgery), Jacobs School of Medicine & Biomedical Sciences

FDA U.S. FOOD & DRUG ADMINISTRATION

KBIO Solutions

케이바이오가 CRO로써 미국 State University of New York at Buffalo 대장암수술의 대학교수들과 국내 개발된 의료기기로 미국임상 FDA와 Pre-Submission 진행했음

미국 뉴욕주립 대학
대장암수술 의료기기 임상시험
CRO 서비스 제공



FDA U.S. FOOD & DRUG ADMINISTRATION

Q202000/S002
JSR Medical Co., Ltd.
Kyungyoon Kang

Re: Written Feedback for Colo-bt

This document is being communicated via e-mail as an attachment. The date on which the Food and Drug Administration (FDA) sent this e-mail is the official date of this correspondence.

This document contains the FDA's written feedback to your Pre-Submission request. This feedback represents our best advice based on the information provided in the Pre-Submission and other information currently known. While our review of your Pre-Submission does not imply that your future submission will necessarily be approved or cleared, FDA intends that this feedback will not change, provided that the information submitted in a future IDE or marketing application is consistent with that provided in this current Pre-Submission and that the data in the future submission do not raise any important new issues materially affecting safety or effectiveness.

If you requested a meeting and this feedback satisfies your needs, you may cancel our upcoming meeting by contacting the lead reviewer. If you still wish to meet, please provide us with your agenda of items and any slides you wish to present no later than two business days prior to the scheduled meeting date per the Pre-Submission Guidance https://www.fda.gov/media/114034/download. If that agenda or presentation contains significant new information, FDA may not be prepared to discuss it. As a reminder, you are expected to submit draft meeting minutes as an amendment to this pre-submission within 15 days of the meeting.

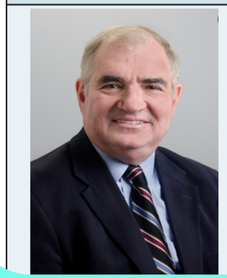
Our feedback to your pre-submission questions is provided below.

KBIO Solutions

케이바이오가 CRO로써 미국 State University of New York at Buffalo
대장암수술의 대학교수들과 국내 개발된 의료기기로
미국임상 FDA와 Pre-Submission 진행했음

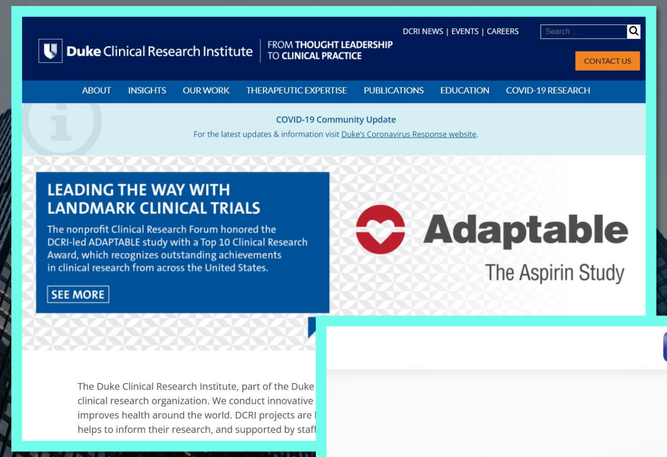
미국 뉴욕주립 대학 대장암수술
의료기기 임상시험 기획하여 추진했음

KBIO CRO Service: USA SUNY Clinical Trial

	Role	Name and Position	Institution
	Principal Investigator	**Mark A. Falvo, MD** • Program Director for Colorectal Fellowship SUNY at Buffalo • Division Chief Colorectal Surgery SUNY at Buffalo • Chief of Colorectal Millard Fillmore Suburban Hospital, Kaleida Health • Assistant Professor, Department of Surgery (Colon and Rectal Surgery), Jacobs School of Medicine & Biomedical Sciences	State University of New York at Buffalo
	Co-Principal Investigator	**Steven D. Schwaitzberg, MD** • Professor and Chair of Department of Surgery (Colon and Rectal Surgery), Jacobs School of Medicine & Biomedical Sciences • Past Chair of the President of Society of American Gastrointestinal and Endoscopic Surgeons)	State University of New York at Buffalo

KBIO Solutions

케이바이오가 CRO로써 한국 AI Software 기업의 미국 임상시험 진행을 위해서 국내 개발된 의료기기로 미국 Duke Clinical Research Institute 섭외



히포티앤씨 GMP 컨설팅 인증달성

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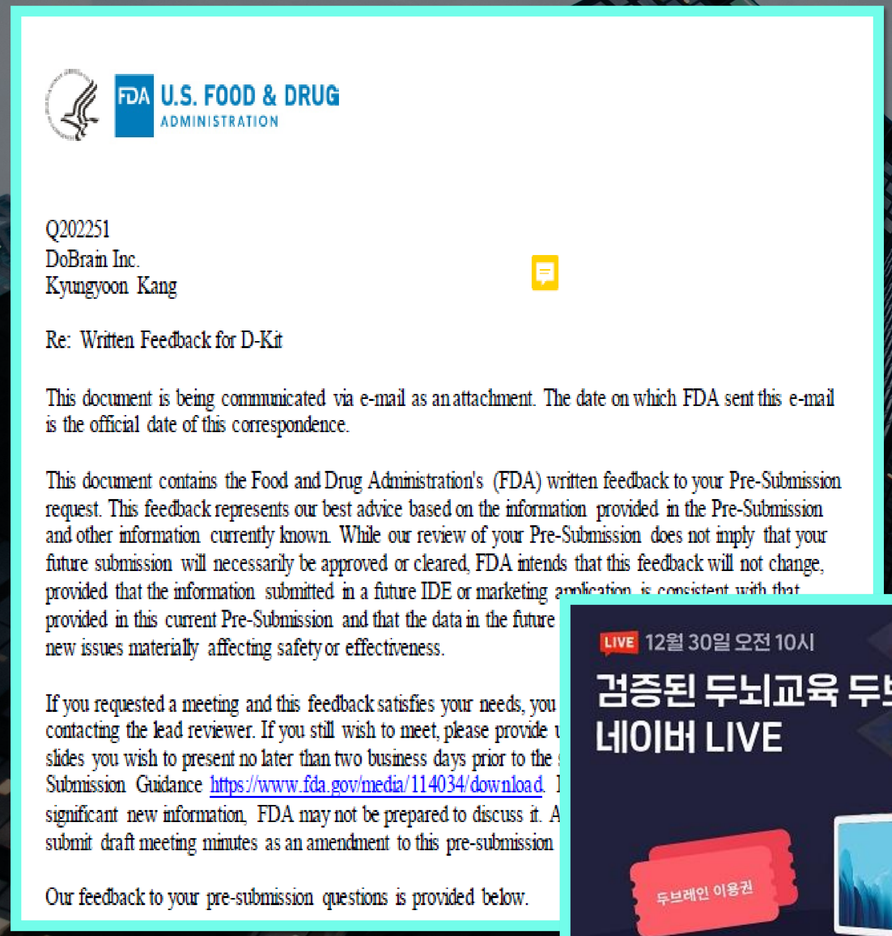
케이바이오가 CRO로써 한국 AI Software 기업의 미국 임상시험 진행을 위해서 국내 개발된 의료기기로 미국 FDA와 Pre-Submission 진행했음



U.S. FOOD & DRUG ADMINISTRATION

Q202251
DoBrain Inc.
Kyungyoon Kang

Re: Written Feedback for D-Kit

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

This document contains the Food and Drug Administration's (FDA) written feedback to your Pre-Submission request. This feedback represents our best advice based on the information provided in the Pre-Submission and other information currently known. While our review of your Pre-Submission does not imply that your future submission will necessarily be approved or cleared, FDA intends that this feedback will not change, provided that the information submitted in a future IDE or marketing application is consistent with that provided in this current Pre-Submission and that the data in the future new issues materially affecting safety or effectiveness.

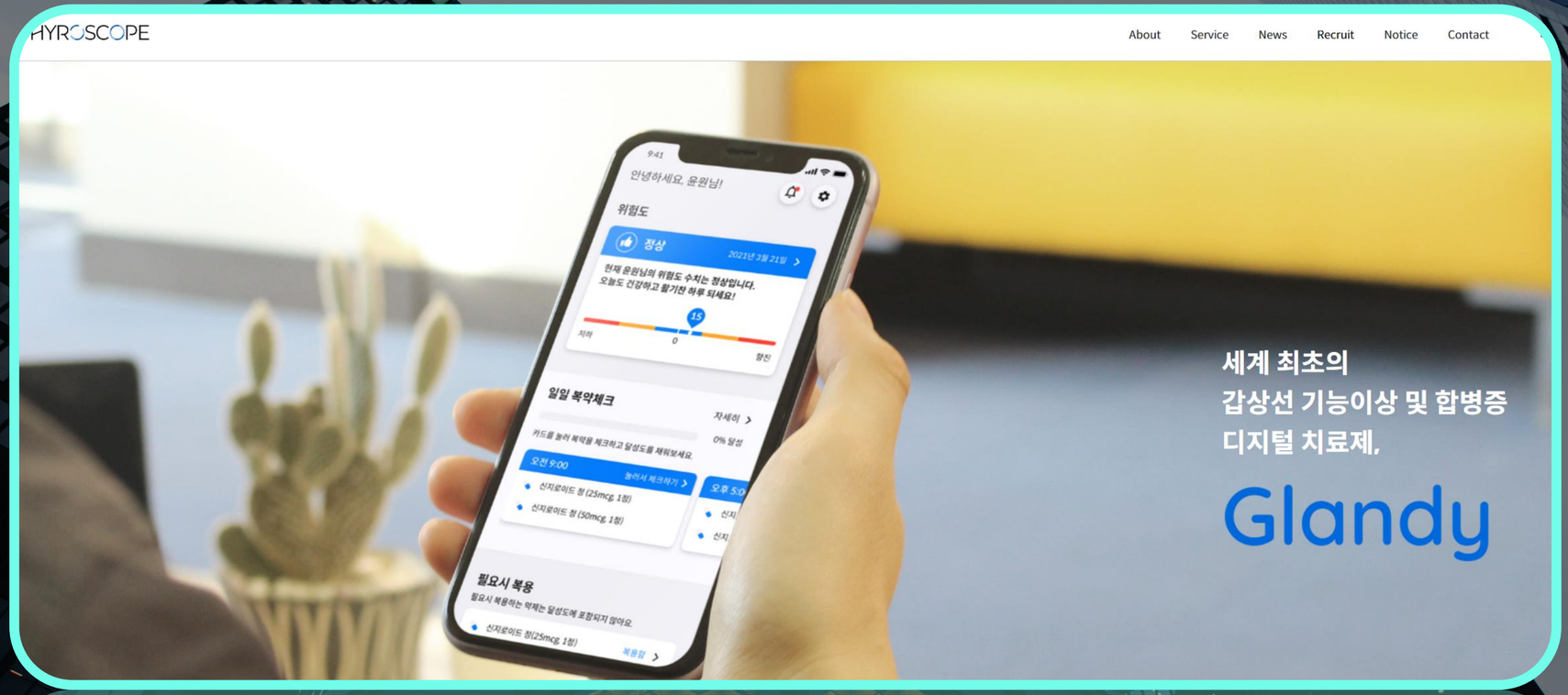
If you requested a meeting and this feedback satisfies your needs, you contacting the lead reviewer. If you still wish to meet, please provide u slides you wish to present no later than two business days prior to the Submission Guidance https://www.fda.gov/media/114034/download. significant new information, FDA may not be prepared to discuss it. A submit draft meeting minutes as an amendment to this pre-submission

Our feedback to your pre-submission questions is provided below.

AI Software 의료기기 FDA와
직접 임상시험 계획 세팅함

KBIO Solutions

케이바이오가 CRO로써 한국 AI Software 기업의 미국 임상시험 진행을 위해서
국내 개발된 의료기기로 미국 FDA와 Pre-Submission 진행했음



미국 임상시험 FDA Pre-Submission
제출하여 임상 프로토콜 조율

KBIO Solutions

케이바이오가 CRO로써 미국 State University of New York at Buffalo 대장암수술의 대학교수들과 국내 개발된 의료기기로 미국임상 FDA와 Pre-Submission 진행했음

2022 코스닥 상장사 노을 AI 진단기기 미국임상시험 FDA와 조율


증권 > 일반

[특징주] 노을, 코스닥 입성 첫날 '강세'

이인아 기자

입력 2022.03.03 09:23

noul

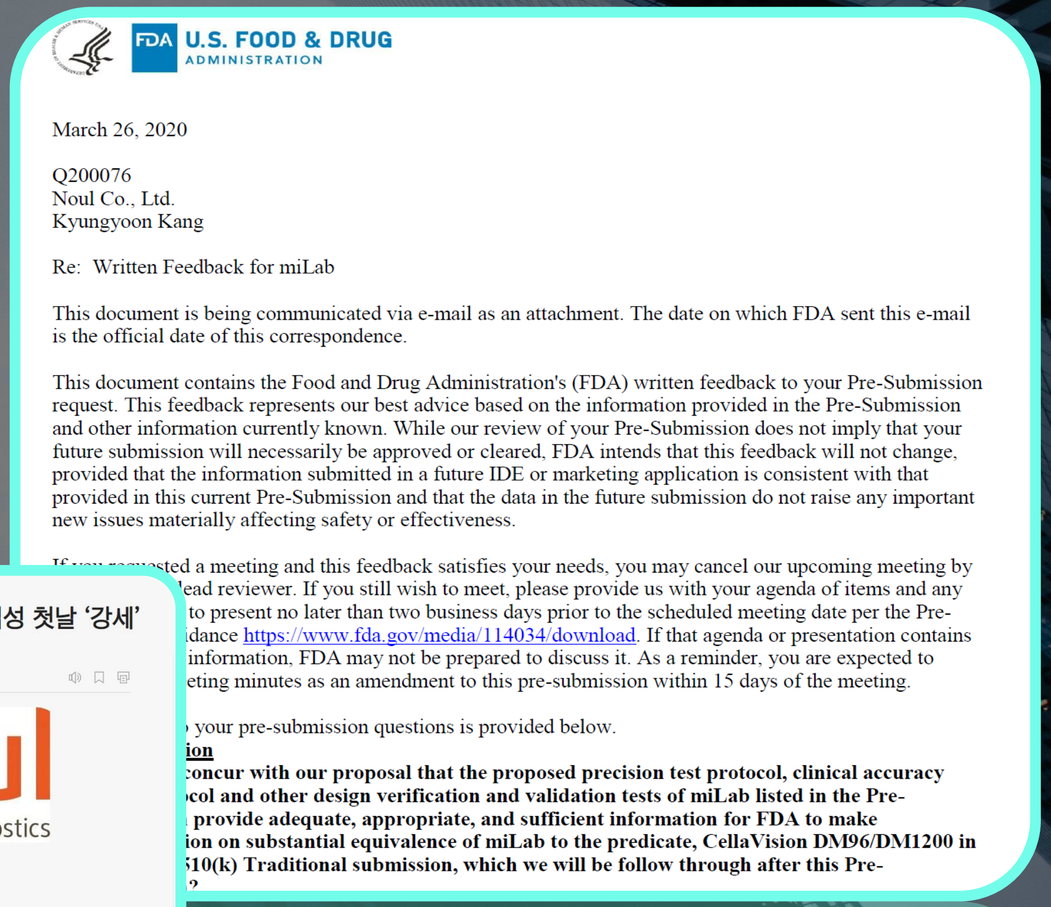
Beyond Diagnostics

노을 CI/노을 제공

노을이 코스닥 상장 첫날 강세를 보이고 있다.

3일 오전 9시 20분 현재 노을 주가는 시초가 대비 4.96% 오른 1만150원에 거래 중이다. 시초가는 공모가(1만원 대비) 3.3% 떨어진 9670원으로 결정됐다.

2015년 설립된 노을은 진단검사 플랫폼 기업이다. 내장형 인공지능(AI) 기술 등을 기반으로 혈액과 조직세포를 분석해 질병을 진단하는 마이랩(miLab) 플랫폼을 개발했다. 마이랩은 마이크로 단위의 진단검사 프로세스가 가능한 수혜기기다.


U.S. FOOD & DRUG ADMINISTRATION

March 26, 2020

Q200076
Noul Co., Ltd.
Kyungyoon Kang

Re: Written Feedback for miLab

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

This document contains the Food and Drug Administration's (FDA) written feedback to your Pre-Submission request. This feedback represents our best advice based on the information provided in the Pre-Submission and other information currently known. While our review of your Pre-Submission does not imply that your future submission will necessarily be approved or cleared, FDA intends that this feedback will not change, provided that the information submitted in a future IDE or marketing application is consistent with that provided in this current Pre-Submission and that the data in the future submission do not raise any important new issues materially affecting safety or effectiveness.

If you requested a meeting and this feedback satisfies your needs, you may cancel our upcoming meeting by ...lead reviewer. If you still wish to meet, please provide us with your agenda of items and any ...to present no later than two business days prior to the scheduled meeting date per the Pre-...dance https://www.fda.gov/media/114034/download. If that agenda or presentation contains ...information, FDA may not be prepared to discuss it. As a reminder, you are expected to ...eting minutes as an amendment to this pre-submission within 15 days of the meeting.

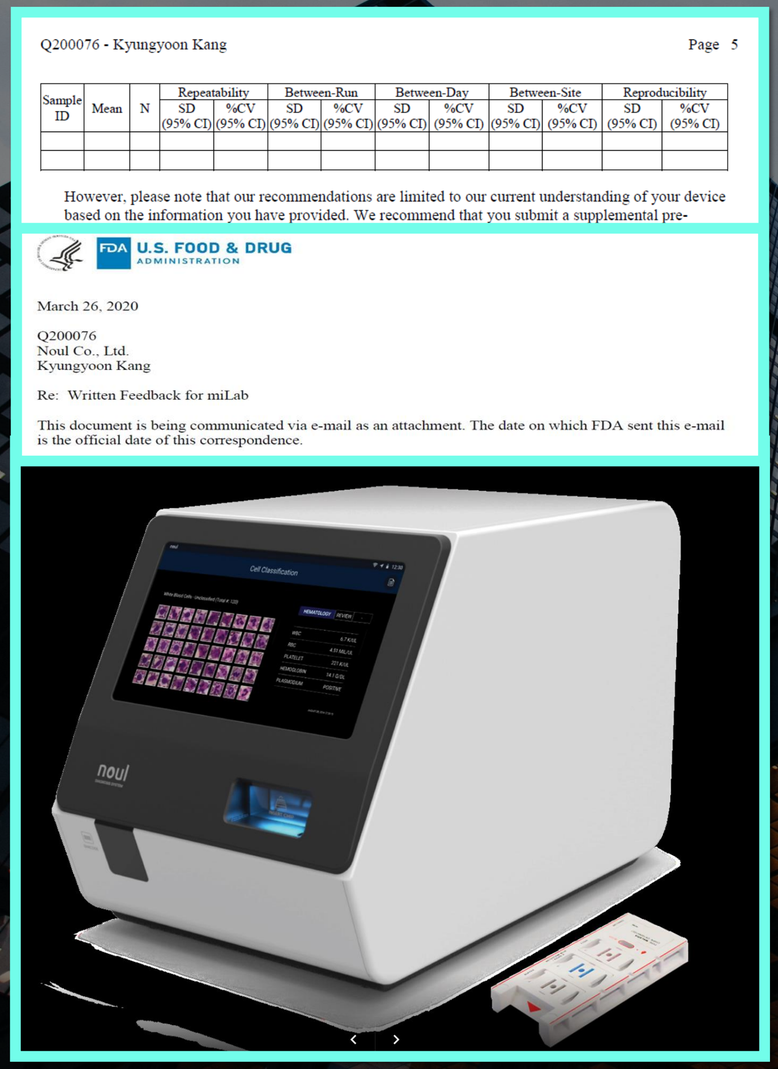
...your pre-submission questions is provided below.

...ion

...concur with our proposal that the proposed precision test protocol, clinical accuracy ...col and other design verification and validation tests of miLab listed in the Pre- ... provide adequate, appropriate, and sufficient information for FDA to make ...ion on substantial equivalence of miLab to the predicate, CellaVision DM96/DM1200 in ...510(k) Traditional submission, which we will be follow through after this Pre-...?

KBIO Solutions

케이바이오가 CRO로써 미국 FDA와 IVD 임상시험 계획 Pre-Submission 2020년 진행



Q200076 - Kyungyoon Kang Page 5

Sample ID	Mean	N	Repeatability		Between-Run		Between-Day		Between-Site		Reproducibility	
			SD (95% CI)	%CV (95% CI)	SD (95% CI)	%CV (95% CI)	SD (95% CI)	%CV (95% CI)	SD (95% CI)	%CV (95% CI)	SD (95% CI)	%CV (95% CI)

However, please note that our recommendations are limited to our current understanding of your device based on the information you have provided. We recommend that you submit a supplemental pre-

FDA U.S. FOOD & DRUG ADMINISTRATION

March 26, 2020

Q200076
Noul Co., Ltd.
Kyungyoon Kang

Re: Written Feedback for miLab

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

IVD 체외진단기기 미국임상시험

FDA와 직접조율 수행했던 이력

케이바이오가 FDA, CE 컨설팅, CRO 임상시험 계약하여 프로젝트 진행한 의료기기 제조사

1. SK바이오팜
2. 카이노스메드: 파킨슨병/다계통위축증 서울아산병원 신약 2상 임상시험설계
3. 존슨앤존슨 미국본사: 시력교정 수술장비 유럽 MDR CE인증
4. 동구바이오제약: 자가지방유래 줄기세포 미국 임상시험
5. 두산전자: Vaccine 주사기
6. 서울대병원 산학협력단: 치과 임플란트 시술 골밀도 측정 CBCT 미국 UCLA임상시험 진행
7. 퓨먼: 치매관련 미국 임상기획
8. 메타바이오메드: 성형외과 안면고정 리프팅 Suture
9. 성원 메디칼: 혈관 중재시술 가이드와이어, Drainage카테터
10. 파인메딕스: 소화기내과 지혈용 클립, 위장 점막하박리술, ESD/EMR Injection카테터
11. 마이크로엔엑스: 치과 마이크로모터, 핸드피스
12. 리메드: 물리치료재활 전자기장파 stimulation, 우울증장애치료 TMS device
13. 유인케어: Virtual Physical Therapy Software with Remote Healthcare (SaMD)
14. 넥스트바이오메디칼: Endoscopic Hemostatic Powder
15. 태웅메디칼: 소화기내과 비혈관 스텐트
16. 타우피엔유: 심부전증 승모판막질환 중재시술 치료 카테터
17. 아주약품: 정형외과 회전근개골접합용 Bioabsorbable Surgical Suture
18. 메디센서: 2형당뇨 당화혈색소 측정기/HbA1C Analyzer
19. 케이메디시스: Arthroplasty Endoscopic Device: 관절내시경
20. 코러스트: Ultrasound Therapy Device/미용/초음파 축농증 치료기
21. 디씨메디칼: 산모 조산진단기기 UAE 병원 임상시험
22. 영케미칼: Bandage Product 중국인증
23. 미국 실리콘밸리 제조사 PhysioCue: 고혈압치료 의료기기
24. 폴란드 정부 바이오나노파크: 3D 프린팅 Orbital Implant, knee implant
25. 제이에스알메디컬: 인공항문대체기기
26. 대한무역투자진흥공사/코트라: 중국 FDA인허가
27. 삼성서울병원 BMCC 바이오중개지원센터: 의료기기 인허가 자문
28. 두브레인: 아동 발달장애치료 Software Device 미국 임상시험 하버드대 교수와 Massachusetts General Hospital 임상시험진행
29. Goldenear Company: 음악가 청력개선 Therapeutic Sound Vaccine 미국 임상
30. INOPUS: 이산화염소 휴대용 멸균기
31. 타이로스코프: 갑상선 질환 환자 스마트 케어 시스템
32. 코넥스트: 지방줄기세포분리 Collagenase Enzyme Smart Device
33. 아모라이프사이언스: (COVID 19 Response Face Mask: Antibacterial Silver Wire)
34. 세종헬스케어: COVID 19 방역 수술용 가운
35. 미로: COVID 19 KF94, KF80, Dental Mask
36. 금동엠텍: 마스크 제조사
37. 앤디포스: COVID 19 Testing Kit
38. 노을: AI IVD Cell Imaging, AI Software 기반 체외진단기
39. 충북창조경제혁신센터: 한국 제조사 사전인허가지원
40. 엠텍에스티에스: 방역 가운
41. 더조은: 수술용 마스크
42. 메디튤립: 내시경용 자동봉합기, 이식형 의약품 주입기

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케이바이오솔루션 소개 자료

KBIO Solutions

(주)디오스파마 무채혈 혈당측정기 MDR CE 미팅

삼천당제약(000250KQ) : 무채혈혈당측정기 생산은 ASUS

[결론] 삼천당제약이 국내독점판매권과 수익공유 권리를 보유하고 있는 무채혈혈당측정기를 대만 ASUS가 위탁생산하는 계약을 체결하였습니다. 유럽 임상시험을 통해 4분기부터 상업화가 가능하며, 국내에서는 2020년 상반기부터 판매가 가능할 것으로 전망됩니다. 동사의 신사업(글로벌제네릭, 바이오시밀러)중에서 가장 빠른 성과가 예상됩니다.

Facts & News

- 삼천당제약이 국내 독점판매권과 해외 매출에 대한 Profit Sharing(수익 공유) 권리를 보유하고 있는 무채혈혈당측정기를 대만 ASUS사가 대량 위탁생산(CMO)계약을 체결
- 무채혈혈당측정기 원천개발은 독일연구소에서 완료했으며, 국내 벤쳐기업 ㈜디오스파마가 개발 및 상업화를 진행 중
- ㈜디오스파마는 독일연구소로부터 글로벌판매권과 독점생산권을 확보
- 삼천당제약은 ㈜디오스파마와 2014년부터 신사업(비안과부문-의료기기 포함) 협업을 진행하였으며, 무채혈혈당측정기에 대한 국내판매권과 Profit Sharing 권리를 2017년에 계약
- 대만의 ASUS사는 2018년 3,915억 TWD(14.3조원)의 매출을 기록한 글로벌 IT 제품 생산, 판매 업체
- ㈜디오스파마와 ASUS사는 무채혈혈당측정기 생산 라인구축협의를 2년 동안 진행하였으며, 5월부터 본격 생산 예정

Comments

- ㈜디오스파마는 2017년 핀란드에서 사전 임상시험을 통해 기존채혈혈당측정기와 정확성을 비교 검증
- 무채혈혈당측정기는 유럽에서 임상시험을 거쳐 헬스케어기기 및 의료기기로 허가를 받아 4분기부터 출시할 계획 (헬스케어기기는 일반인을 대상으로 하는 혈당결과 분류기, 의료기기는 정확한 혈당 측정수치를 제공)
- 혈당모니터링 기기 시장은 2016년 155.5억 달러에서 연평균 성장률 11.8%로 2021년 271.7억 달러로 전망. 국내 혈당측정기 시장은 1,300억원으로 추정
- 기존 채혈혈당측정기는 란셋(Lanset)을 통해 혈액을 추출, 스트립(Strip)에 올려 측정기기(Meter)를 통해 결과 분석
- 무채혈혈당측정기 장점은 **1) 채혈과정이 없어 고통 없이 측정이 가능, 2) 스트립의 소모가 없어 제조원가 절감으로 수익성 향상(OPM 20% → 40% 이상), 3) 일반인 건강관리 차원의 사용이 가능해 시장확대 전망**
- 일정대로 유럽에서 무채혈혈당측정기가 허가승인(2019.3Q)에 성공한다면, 2018년 7월에 정부에서 발표한 의료기기 규제혁신 및 산업육성 방안(체외진단기기 시장진입 소요기간 단축, 390일→80일 이내)을 통해 빠르게 2020년 상반기에 국내 상업화 가능
- 동사에서 진행하고 있는 신사업(제네릭 의약품 수출, 바이오시밀러 개발 및 상업화, 혁신형 의료기기) 중 가장 **빠르게 수익을 실현할 수 있는 사업으로 판단**

케이프투자증권

그림1. 기존 채혈혈당측정기

자료: 삼천당제약, 케이프투자증권 리서치본부

그림 2. 삼천당제약 무채혈혈당측정기

자료: 삼천당제약, 케이프투자증권 리서치본부

그림 3. 자가혈당 측정기 글로벌시장 현황

자료: 삼천당제약, 케이프투자증권 리서치본부

그림 4. 무채혈 혈당 측정기 출시계획

자료: 삼천당제약, 케이프투자증권 리서치본부

Compliance

- 동 자료에 게시된 내용들은 본인의 의견을 정확히 반영하고 있으며, 외부의 부당한 압력이나 간섭없이 작성되었음을 확인합니다.
- 당사는 공표일 현재 상기 종목의 발행주식을 1%이상 보유하고 있지 않습니다.
- 당사는 동 자료를 기관투자자 또는 제3자에게 사전제공한 사실이 없습니다.
- 당사는 동 자료에 언급된 종목과 계열회사의 관계가 아닙니다.
- 조사분석 담당자는 공표일 기준 동 자료에 언급된 종목과 재산적 이해관계가 없습니다.

KBIO Solutions

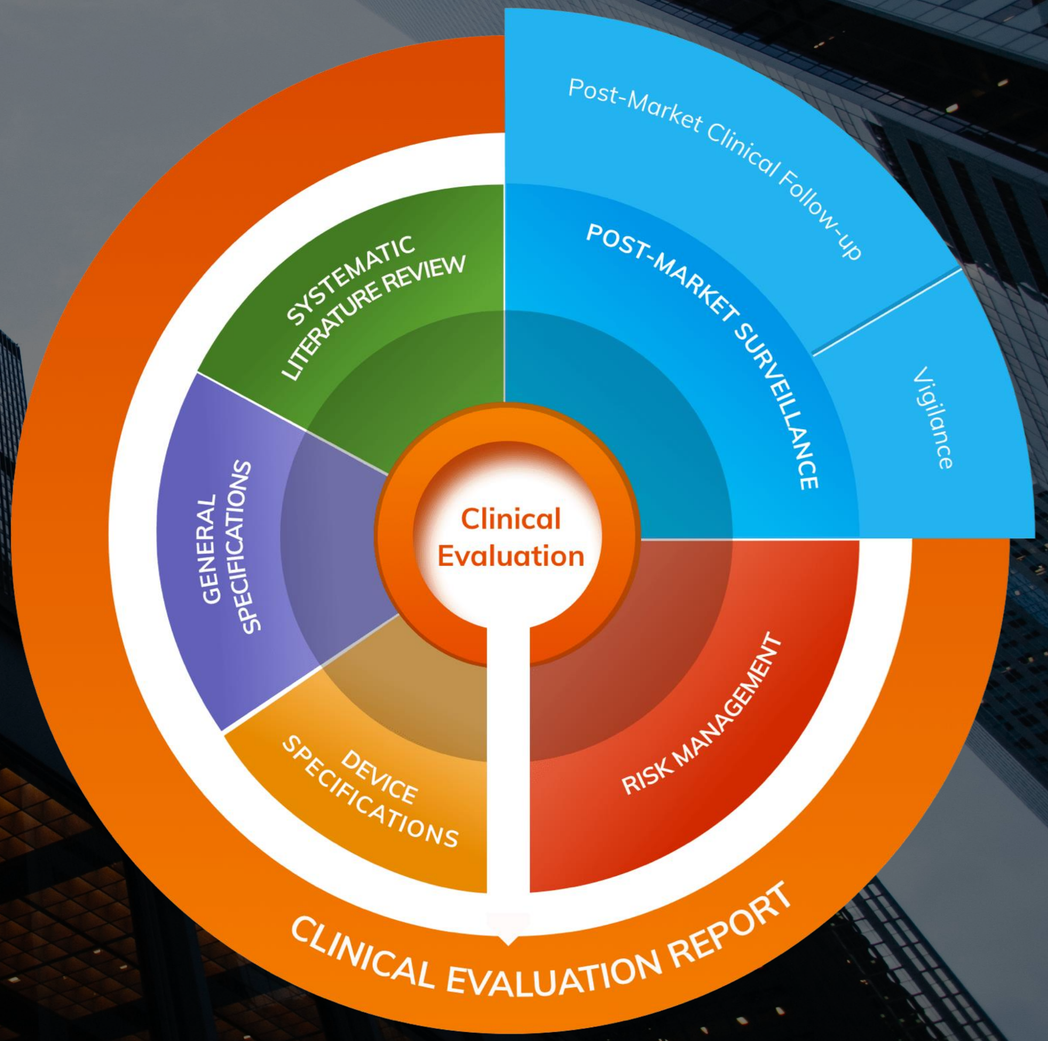
(주)오큐라이트 MDR - CER 작성: EU MDR Clinical Evaluation Report

CER:

- Its purpose is to prove your device performs as intended without compromising the safety of its end users.

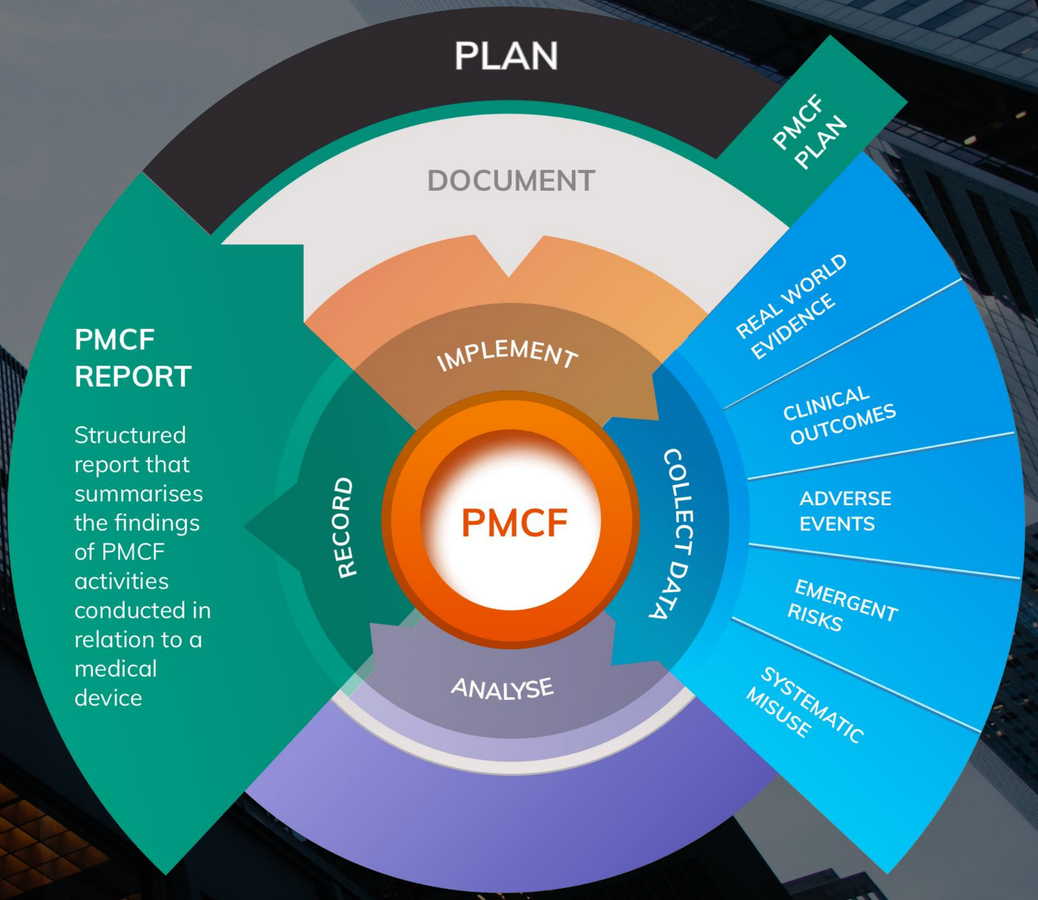
- Article 61 of EU MDR requires every medical device manufacturer to document the clinical evaluation of their device in a CER. This requirement is expanded upon in Annex XIV Part A, which states:

  - *The results of the clinical evaluation and the clinical evidence on which it is based shall be documented in a clinical evaluation report which shall support the assessment of the conformity of the device.*



KBIO Solutions

EU MDR 요건충족을 위한 iChopper PSUR/PMCF 컨설팅 제공



The continuous clinical evidence collection process in Post-Market Clinical Follow-up(PMCF)

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MDR CE 인증 컨설팅 제공: iChopper MDR IIb 등급 컨설팅 진행

MDR CE 인증을 위한
MDR 심사 파일 자문제공

1 iChopper MDR Class IIb CE 인증 전략설계

2 MDR Technical Documentation
기업 의료기기 맞춤형 MDR 기술문서 준비

3 General Safety & Performance Requirements 자문제공

4 ㈜오큐라이트에서 필요한 초기성능시험, 생물학적안전성시험, 밸리데이션 시험 모두 완료하여 MDR 심사접수 및 인증기관의 보완요청 대응에 대한 컨설팅 제공

㈜오큐라이트
Best Light for Eye

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MDR CE 인증 컨설팅 제공: iChopper MDR IIb 등급 컨설팅 진행

5 성능시험, 안전성시험 등 완료이후 MDR CE 보완대응 수행 — COMPLETE

4 MDR CE 인증에 필요한 임상평가보고서 Clinical Evaluation Report 작성

3 MDR CE인증을 위한 General Safety & Performance Requirements 작성

2 iChopper MDR 기술문서준비: Technical Documentation 작성 — IN PROGRESS

1 2023년 ㈜오큐라이트 MDR 프로그램 개시 — IN PROGRESS

iChopper MDR CE 인증취득을 위해
Technical Documentation, 기술문서, GSPR, CER 임상평가서
준비하여 심사접수 세팅 및 CE 보완요청사항 대응

㈜오큐라이트
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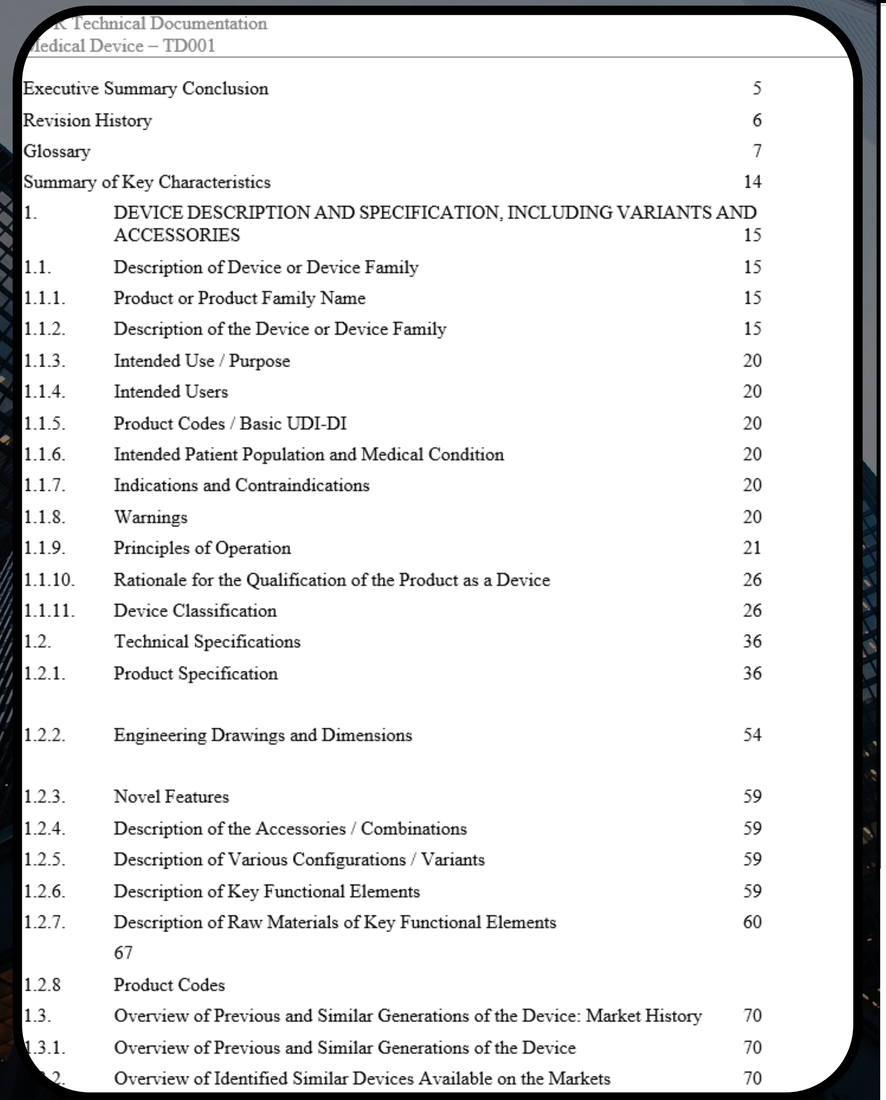
Consulting

MDR CE 인증 컨설팅 제공:
디오스파마 무채혈 혈당측정기

CE MDR 접수에 필요한 MDR 기술문서 Technical Documentation 작성 컨설팅 제공



Overview of Identified Similar Devices Available on the Markets 70
Overview of Previous and Similar Generations of the Device 70
Overview of Previous and Similar Generations of the Device: Market History 70
Product Codes

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Consulting

MDR CE 인증 컨설팅 제공:
디오스파마 무채혈 혈당측정기

CE MDR 접수에 필요한 MDR General Safety & Performance Requirements 파일 준비 컨설팅 제공

GSPR	Description	Applicable?	Methods Applied	Standards & Solutions	Evidence
7	Devices shall be designed, manufactured, and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer	Yes	Design considers packaging requirements. Packaged product has been verified through shipping and transit testing. Product was stored at extremes of temperature and humidity.	EN ISO 13585 QMS EN ISO 15223-1 Labelling ISTA 2A Testing	Design procedure XXXXXX, rev XX located in document management system QMS certificate XXXXXX Package design drawings XXXXXX, rev XX located in docuent management system Product label XXXXXXX, rev XX found in section XX of Tech File XX ISTA 2A test report title XXXXX, dated XX/XX/XX found in section XX of Tech File XX Storage condition test report title XXXXX, dated XX/XX/XX found in section XX of Tech File XX

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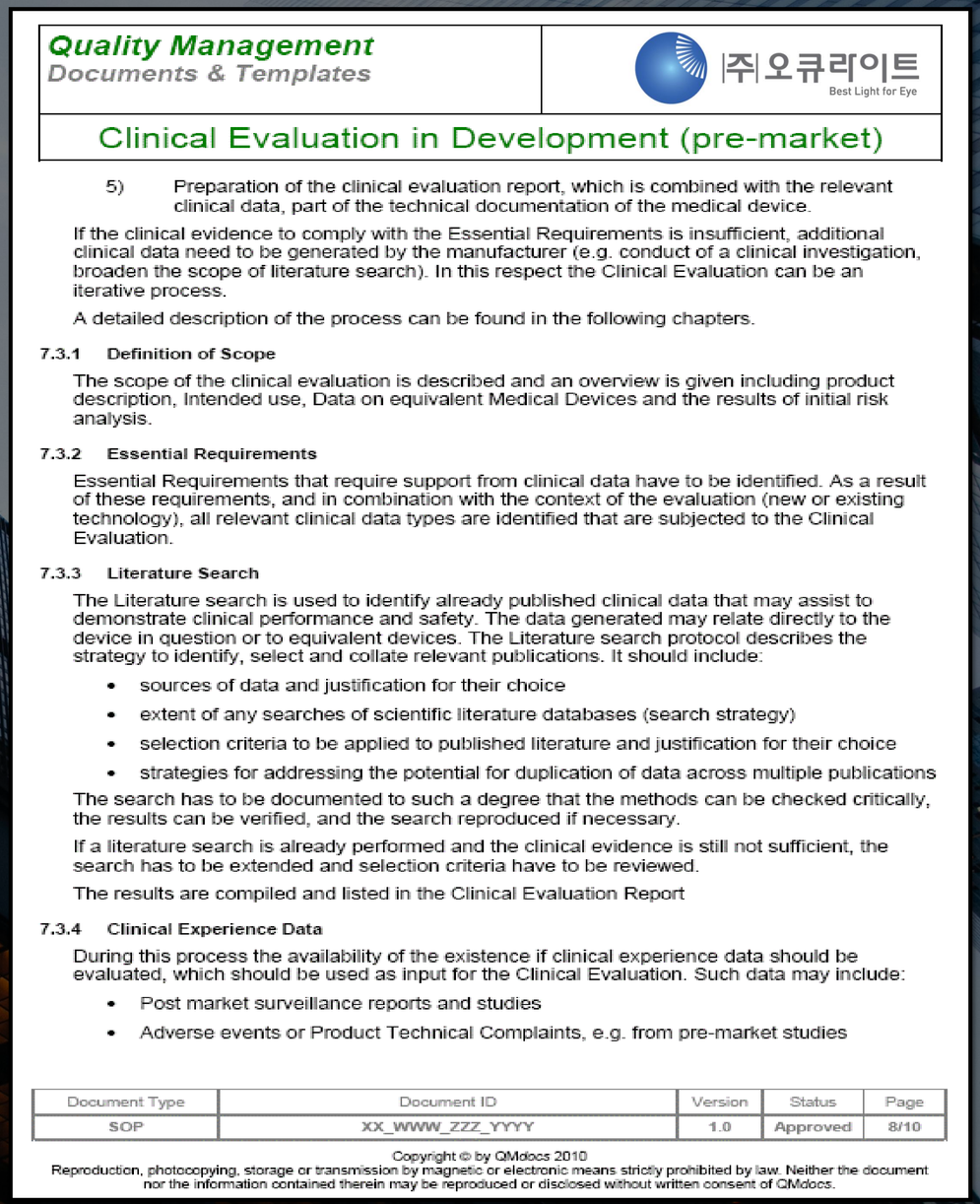
MDR CE 인증 컨설팅 제공:
(주)오큐라이트 iChopper

iChopper CE MDR 접수에 필요한 Clinical Evaluation Report 파일 준비



Quality Management
Documents & Templates

(주)오큐라이트 Best Light for Eye

Clinical Evaluation in Development (pre-market)

5) Preparation of the clinical evaluation report, which is combined with the relevant clinical data, part of the technical documentation of the medical device.

If the clinical evidence to comply with the Essential Requirements is insufficient, additional clinical data need to be generated by the manufacturer (e.g. conduct of a clinical investigation, broaden the scope of literature search). In this respect the Clinical Evaluation can be an iterative process.

A detailed description of the process can be found in the following chapters.

7.3.1 Definition of Scope

The scope of the clinical evaluation is described and an overview is given including product description, Intended use, Data on equivalent Medical Devices and the results of initial risk analysis.

7.3.2 Essential Requirements

Essential Requirements that require support from clinical data have to be identified. As a result of these requirements, and in combination with the context of the evaluation (new or existing technology), all relevant clinical data types are identified that are subjected to the Clinical Evaluation.

7.3.3 Literature Search

The Literature search is used to identify already published clinical data that may assist to demonstrate clinical performance and safety. The data generated may relate directly to the device in question or to equivalent devices. The Literature search protocol describes the strategy to identify, select and collate relevant publications. It should include:

- sources of data and justification for their choice
- extent of any searches of scientific literature databases (search strategy)
- selection criteria to be applied to published literature and justification for their choice
- strategies for addressing the potential for duplication of data across multiple publications

The search has to be documented to such a degree that the methods can be checked critically, the results can be verified, and the search reproduced if necessary.

If a literature search is already performed and the clinical evidence is still not sufficient, the search has to be extended and selection criteria have to be reviewed.

The results are compiled and listed in the Clinical Evaluation Report

7.3.4 Clinical Experience Data

During this process the availability of the existence if clinical experience data should be evaluated, which should be used as input for the Clinical Evaluation. Such data may include:

- Post market surveillance reports and studies
- Adverse events or Product Technical Complaints, e.g. from pre-market studies

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EU MDR 요건충족을 위한 iChopper CER 작성: Clinical Evaluation Report

What do MDR and MEDDEV 2.7.1 Rev 4 say about the clinical evaluation report (CER)?

MEDDEV 2.7.1 Rev 4 states that your CER should outline the four different stages of clinical evaluation:

- **Stage 0 - Scope**: The scope and context of the clinical evaluation, including the product being tested and any sizes or settings covered in the evaluation. This also includes an explanation of the technology the device is based on and any claims about its performance or safety.
- **Stage 1 - Identification of pertinent data**: This may include any data generated by the manufacturer, including premarket clinical investigations, as well as data from literature.
- **Stage 2 - Appraisal of data**: In this stage the data is appraised and the validity of each data set must be determined, as well as its relevance to the clinical evaluation and how heavily it should be weighed in the overall evaluation.
- **Stage 3 - Analysis of clinical data**: This is the actual analysis of the clinical data, which should include the benefits and risks of the device, explain the acceptability of the benefit/risk profile, and address any residual risks, uncertainties, or unanswered questions.

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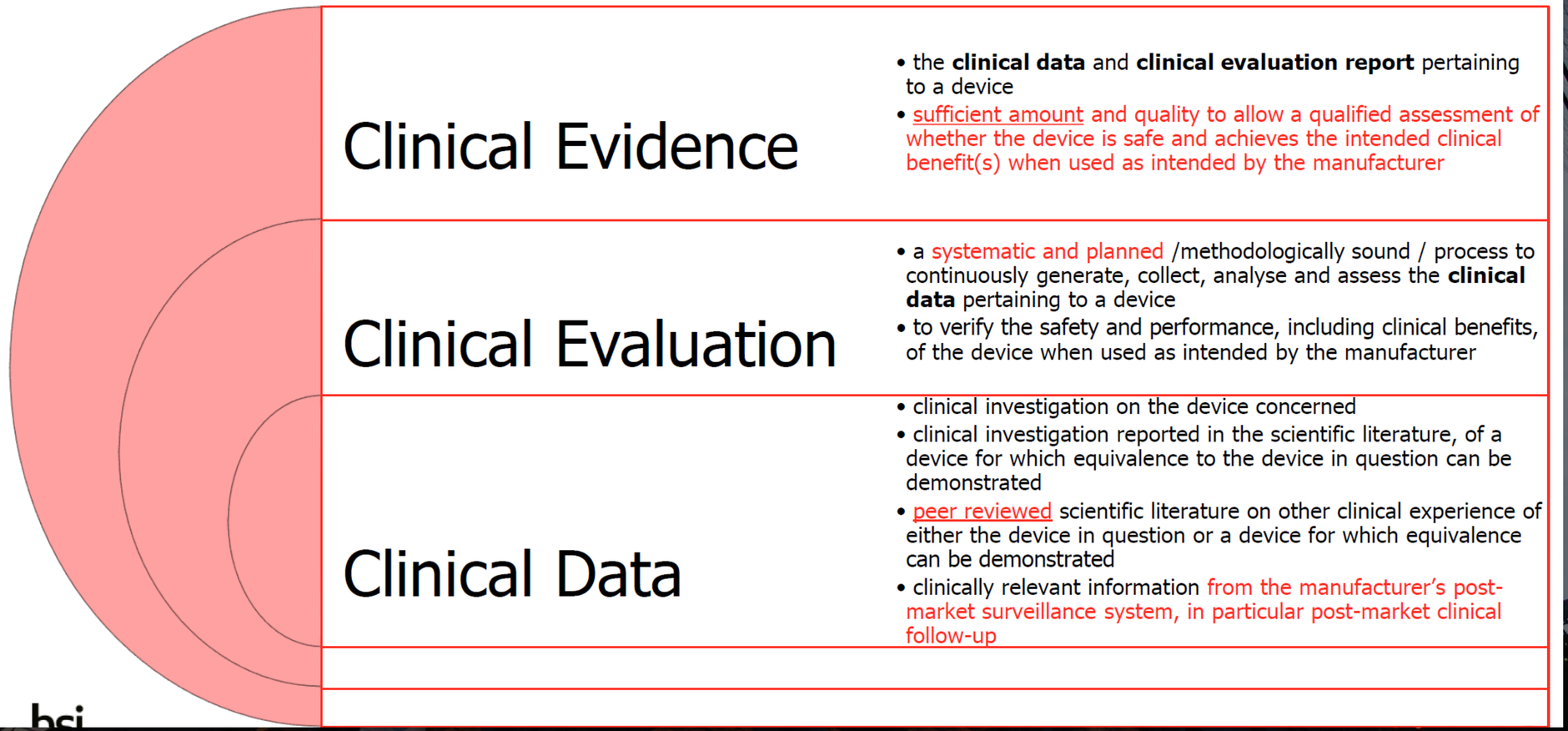
EU MDR 요건충족을 위한 iChopper CER 작성: Clinical Evaluation Report

Clinical Evidence – MedDev 2.7.1 & MDR



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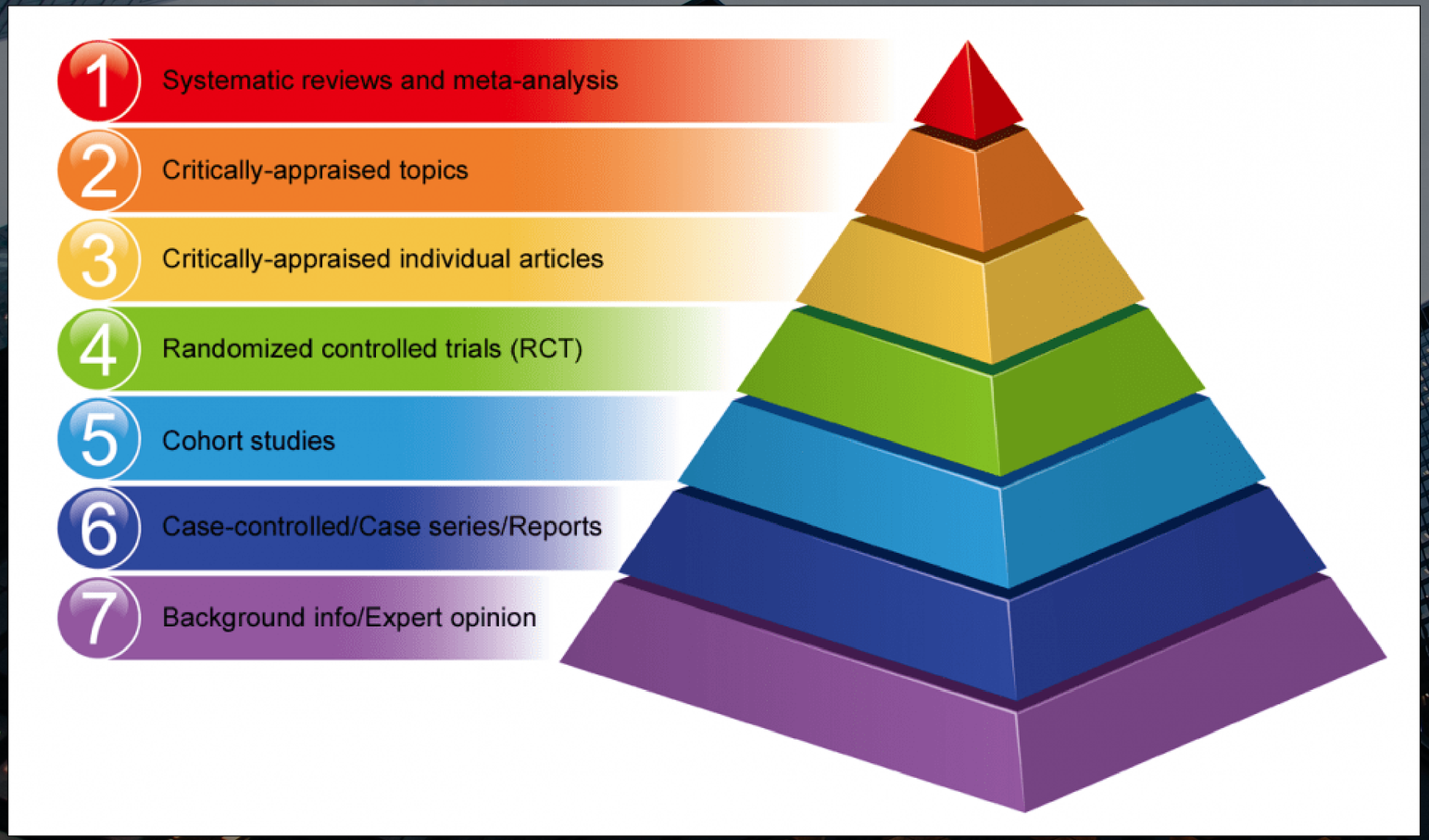
EU MDR 요건충족을 위한 iChopper CER 작성: 메타분석방식 적용



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Meta-analysis is a statistical method that combines and synthesizes multiple studies and integrates their results. Meta-analysis increases the sample size, and in turn, the power to study the effects of interest by combining primary studies and providing a precise estimate of the effects. Data synthesized from meta-analyses are usually more beneficial than the results of narrative reviews. In a meta-analysis, the decisions are transparent, and statistical analysis yields an objective measure of the integrated quantitative evidence.

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How to conduct a meta-analysis in eight steps: a practical guide

EDITORIAL

Check for updates

How to conduct a meta-analysis in eight steps: a practical guide

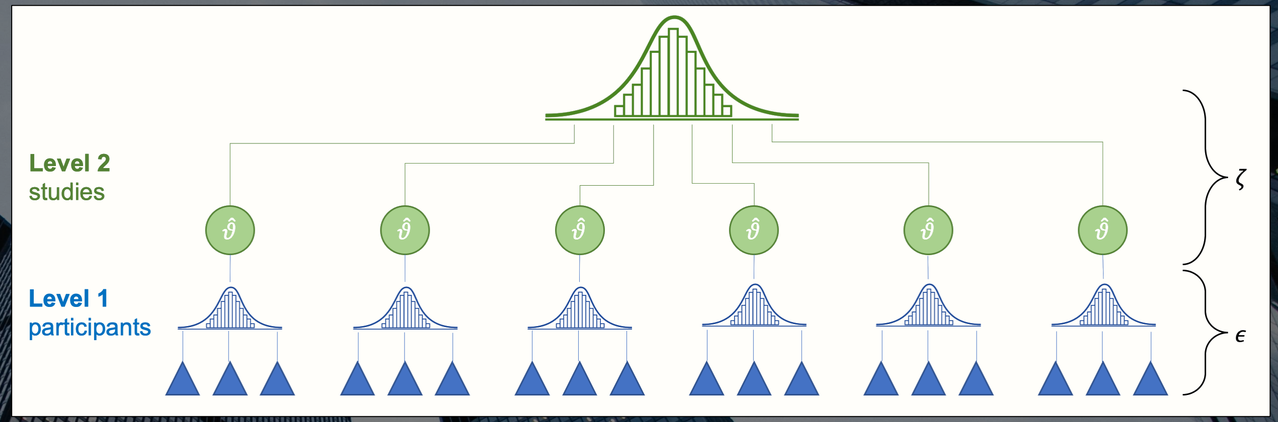
Christopher Hansen[1] · Holger Steinmetz[2] · Jörn Block[3,4,5]

Published online: 30 November 2021

1 Introduction

> "Scientists have known for centuries that a single study will not resolve a major issue. Indeed, a small sample study will not even resolve a minor issue. Thus, the foundation of science is the cumulation of knowledge from the results of many studies." (Hunter et al. 1982, p. 10)

Meta-analysis is a central method for knowledge accumulation in many scientific fields (Aguinis et al. 2011c; Kepes et al. 2013). Similar to a narrative review, it serves as a synopsis of a research question or field. However, going beyond a narrative summary of key findings, a meta-analysis adds value in providing a quantitative assessment of the relationship between two target variables or the effectiveness of an intervention (Gurevitch et al. 2018). Also, it can be used to test competing theoretical assumptions against each other or to identify important moderators where the results of different primary studies differ from each other (Aguinis et al. 2011b; Bergh et al. 2016). Rooted in the synthesis of the effectiveness of medical and psychological interventions in the 1970s (Glass 2015; Gurevitch et al. 2018), meta-analysis is nowadays also an established method in management research and related fields.



Meta-Analysis

Source:
Management Review Quarterly (2022) 72:1–19
https://doi.org/10.1007/s11301-021-00247-4

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Consulting: 주식회사 오큐라이트 iChopper MDR 컨설팅 진행

BSI Class IIb 심사를 의한 BSI 절차에 맞는 MDR CE 인증 컨설팅 제공: iChopper

- Technical Documentation
- GSPR
- CER
- PMS
- Risk Management 파일

MDR 심사 보완요청 1차, 2차, 3차 라운드 대응

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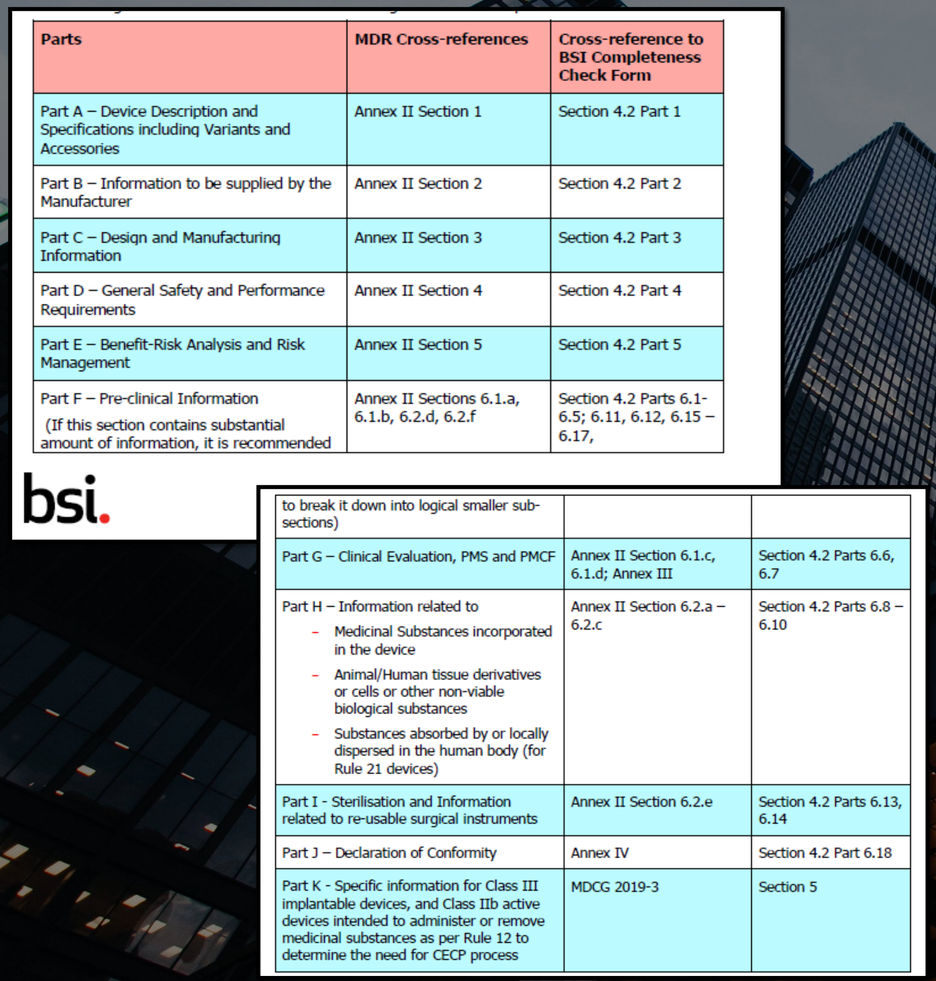
MDR 컨설팅 진행



Parts	MDR Cross-references	Cross-reference to BSI Completeness Check Form
Part A – Device Description and Specifications including Variants and Accessories	Annex II Section 1	Section 4.2 Part 1
Part B – Information to be supplied by the Manufacturer	Annex II Section 2	Section 4.2 Part 2
Part C – Design and Manufacturing Information	Annex II Section 3	Section 4.2 Part 3
Part D – General Safety and Performance Requirements	Annex II Section 4	Section 4.2 Part 4
Part E – Benefit-Risk Analysis and Risk Management	Annex II Section 5	Section 4.2 Part 5
Part F – Pre-clinical Information (If this section contains substantial amount of information, it is recommended	Annex II Sections 6.1.a, 6.1.b, 6.2.d, 6.2.f	Section 4.2 Parts 6.1-6.5; 6.11, 6.12, 6.15 – 6.17,

bsi.

to break it down into logical smaller sub-sections)		
Part G – Clinical Evaluation, PMS and PMCF	Annex II Section 6.1.c, 6.1.d; Annex III	Section 4.2 Parts 6.6, 6.7
Part H – Information related to – Medicinal Substances incorporated in the device – Animal/Human tissue derivatives or cells or other non-viable biological substances – Substances absorbed by or locally dispersed in the human body (for Rule 21 devices)	Annex II Section 6.2.a – 6.2.c	Section 4.2 Parts 6.8 – 6.10
Part I - Sterilisation and Information related to re-usable surgical instruments	Annex II Section 6.2.e	Section 4.2 Parts 6.13, 6.14
Part J – Declaration of Conformity	Annex IV	Section 4.2 Part 6.18
Part K - Specific information for Class III implantable devices, and Class IIb active devices intended to administer or remove medicinal substances as per Rule 12 to determine the need for CECP process	MDCG 2019-3	Section 5

BSI Class IIb 심사를 의한 BSI 절차에 맞는 MDR CE 인증 컨설팅 제공:
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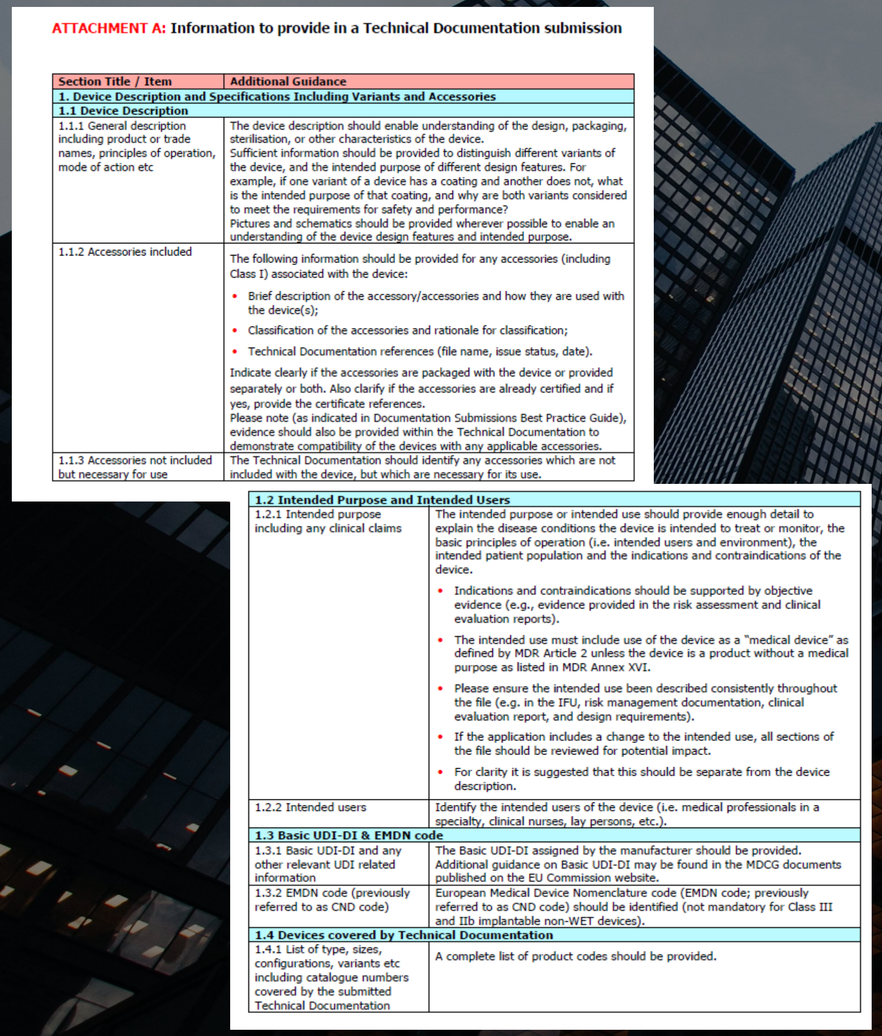

ATTACHMENT A: Information to provide in a Technical Documentation submission

Section Title / Item	Additional Guidance
1. Device Description and Specifications Including Variants and Accessories	
1.1 Device Description	
1.1.1 General description including product or trade names, principles of operation, mode of action etc	The device description should enable understanding of the design, packaging, sterilisation, or other characteristics of the device. Sufficient information should be provided to distinguish different variants of the device, and the intended purpose of different design features. For example, if one variant of a device has a coating and another does not, what is the intended purpose of that coating, and why are both variants considered to meet the requirements for safety and performance? Pictures and schematics should be provided wherever possible to enable an understanding of the device design features and intended purpose.
1.1.2 Accessories included	The following information should be provided for any accessories (including Class I) associated with the device: • Brief description of the accessory/accessories and how they are used with the device(s); • Classification of the accessories and rationale for classification; • Technical Documentation references (file name, issue status, date). Indicate clearly if the accessories are packaged with the device or provided separately or both. Also clarify if the accessories are already certified and if yes, provide the certificate references. Please note (as indicated in Documentation Submissions Best Practice Guide), evidence should also be provided within the Technical Documentation to demonstrate compatibility of the devices with any applicable accessories.
1.1.3 Accessories not included but necessary for use	The Technical Documentation should identify any accessories which are not included with the device, but which are necessary for its use.
1.2 Intended Purpose and Intended Users	
1.2.1 Intended purpose including any clinical claims	The intended purpose or intended use should provide enough detail to explain the disease conditions the device is intended to treat or monitor, the basic principles of operation (i.e. intended users and environment), the intended patient population and the indications and contraindications of the device. • Indications and contraindications should be supported by objective evidence (e.g., evidence provided in the risk assessment and clinical evaluation reports). • The intended use must include use of the device as a "medical device" as defined by MDR Article 2 unless the device is a product without a medical purpose as listed in MDR Annex XVI. • Please ensure the intended use been described consistently throughout the file (e.g. in the IFU, risk management documentation, clinical evaluation report, and design requirements). • If the application includes a change to the intended use, all sections of the file should be reviewed for potential impact. • For clarity it is suggested that this should be separate from the device description.
1.2.2 Intended users	Identify the intended users of the device (i.e. medical professionals in a specialty, clinical nurses, lay persons, etc.).
1.3 Basic UDI-DI & EMDN code	
1.3.1 Basic UDI-DI and any other relevant UDI related information	The Basic UDI-DI assigned by the manufacturer should be provided. Additional guidance on Basic UDI-DI may be found in the MDCG documents published on the EU Commission website.
1.3.2 EMDN code (previously referred to as CND code)	European Medical Device Nomenclature code (EMDN code; previously referred to as CND code) should be identified (not mandatory for Class III and IIb implantable non-WET devices).
1.4 Devices covered by Technical Documentation	
1.4.1 List of type, sizes, configurations, variants etc including catalogue numbers covered by the submitted Technical Documentation	A complete list of product codes should be provided.

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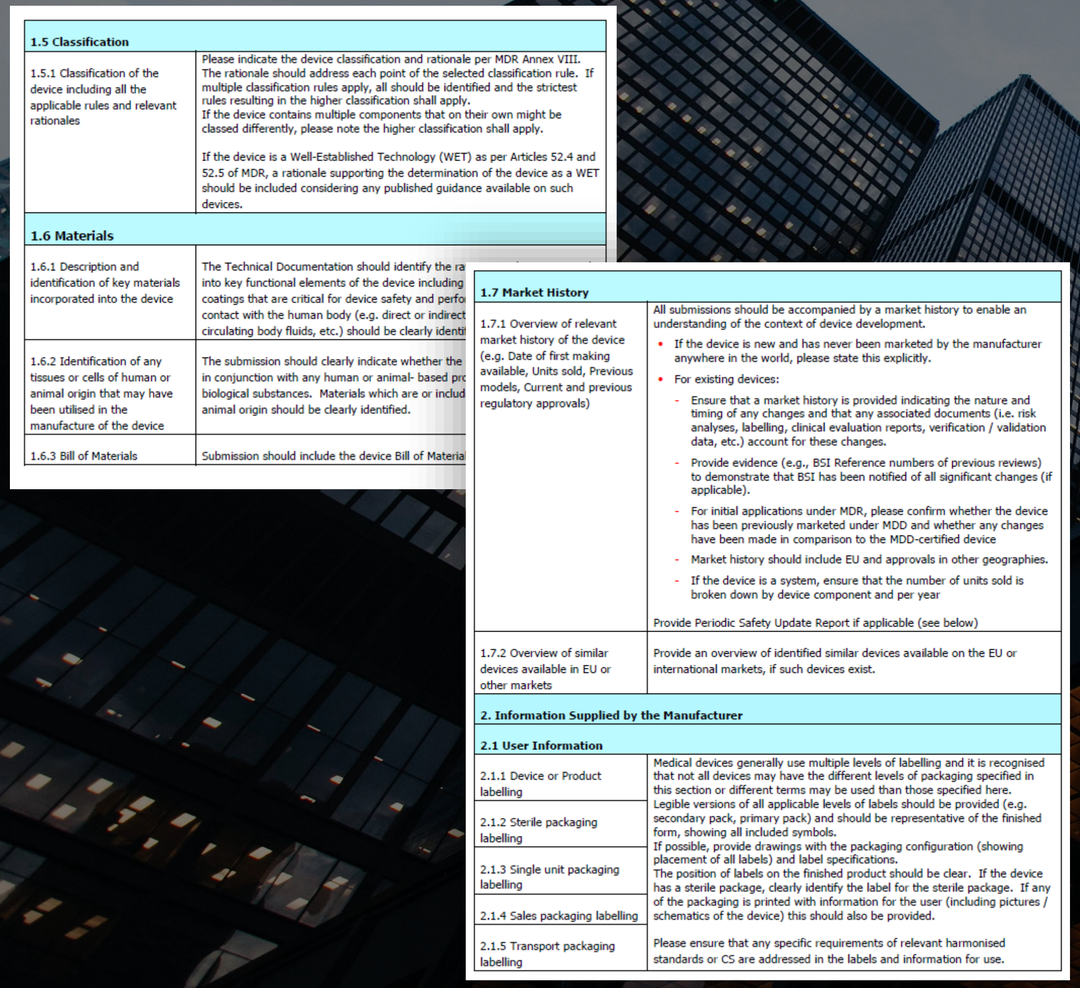
MDR 컨설팅 진행



1.5 Classification	
1.5.1 Classification of the device including all the applicable rules and relevant rationales	Please indicate the device classification and rationale per MDR Annex VIII. The rationale should address each point of the selected classification rule. If multiple classification rules apply, all should be identified and the strictest rules resulting in the higher classification shall apply. If the device contains multiple components that on their own might be classed differently, please note the higher classification shall apply. If the device is a Well-Established Technology (WET) as per Articles 52.4 and 52.5 of MDR, a rationale supporting the determination of the device as a WET should be included considering any published guidance available on such devices.
1.6 Materials	
1.6.1 Description and identification of key materials incorporated into the device	The Technical Documentation should identify the ra into key functional elements of the device including coatings that are critical for device safety and perfo contact with the human body (e.g. direct or indirect circulating body fluids, etc.) should be clearly identi
1.6.2 Identification of any tissues or cells of human or animal origin that may have been utilised in the manufacture of the device	The submission should clearly indicate whether the in conjunction with any human or animal- based pr biological substances. Materials which are or includ animal origin should be clearly identified.
1.6.3 Bill of Materials	Submission should include the device Bill of Materia

1.7 Market History	
1.7.1 Overview of relevant market history of the device (e.g. Date of first making available, Units sold, Previous models, Current and previous regulatory approvals)	All submissions should be accompanied by a market history to enable an understanding of the context of device development. • If the device is new and has never been marketed by the manufacturer anywhere in the world, please state this explicitly. • For existing devices: - Ensure that a market history is provided indicating the nature and timing of any changes and that any associated documents (i.e. risk analyses, labelling, clinical evaluation reports, verification / validation data, etc.) account for these changes. - Provide evidence (e.g., BSI Reference numbers of previous reviews) to demonstrate that BSI has been notified of all significant changes (if applicable). - For initial applications under MDR, please confirm whether the device has been previously marketed under MDD and whether any changes have been made in comparison to the MDD-certified device - Market history should include EU and approvals in other geographies. - If the device is a system, ensure that the number of units sold is broken down by device component and per year Provide Periodic Safety Update Report if applicable (see below)
1.7.2 Overview of similar devices available in EU or other markets	Provide an overview of identified similar devices available on the EU or international markets, if such devices exist.
2. Information Supplied by the Manufacturer	
2.1 User Information	
2.1.1 Device or Product labelling	Medical devices generally use multiple levels of labelling and it is recognised that not all devices may have the different levels of packaging specified in this section or different terms may be used than those specified here. Legible versions of all applicable levels of labels should be provided (e.g. secondary pack, primary pack) and should be representative of the finished form, showing all included symbols. If possible, provide drawings with the packaging configuration (showing placement of all labels) and label specifications. The position of labels on the finished product should be clear. If the device has a sterile package, clearly identify the label for the sterile package. If any of the packaging is printed with information for the user (including pictures / schematics of the device) this should also be provided. Please ensure that any specific requirements of relevant harmonised standards or CS are addressed in the labels and information for use.
2.1.2 Sterile packaging labelling	
2.1.3 Single unit packaging labelling	
2.1.4 Sales packaging labelling	
2.1.5 Transport packaging labelling	

BSI Class IIb 심사를 의한 BSI 절차에 맞는 MDR CE 인증 컨설팅 제공: iChopper

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MDR 심사 보완요청 1차, 2차, 3차 라운드 대응

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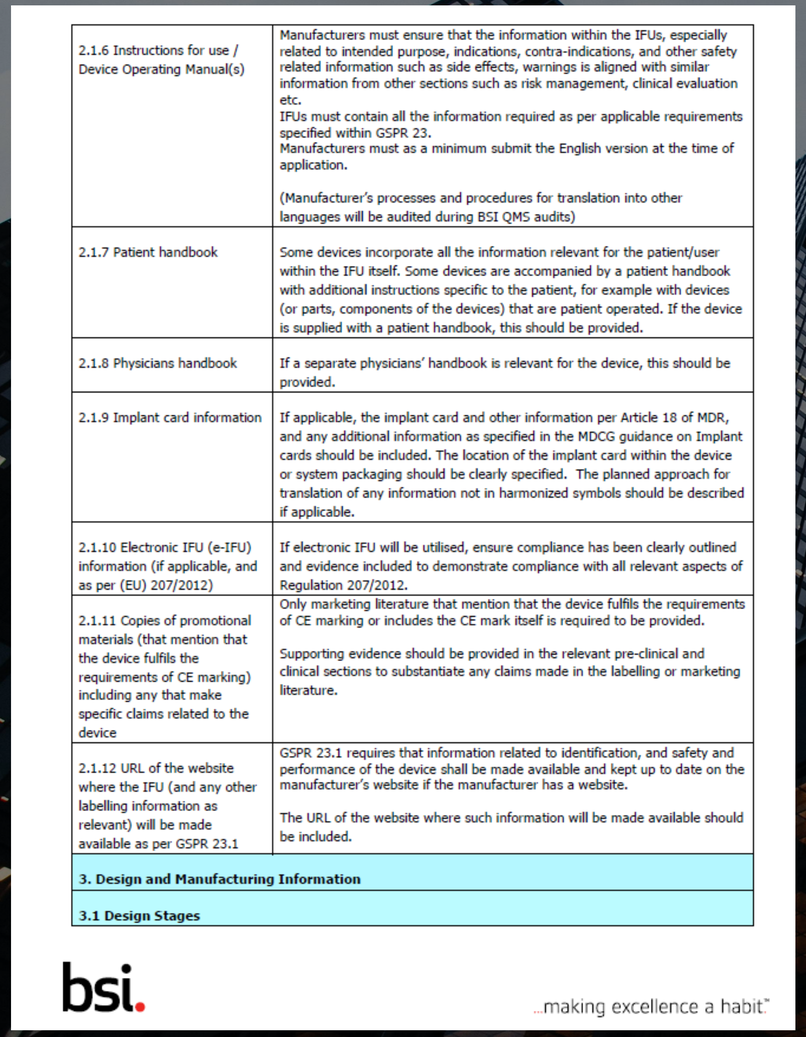
MDR 컨설팅 진행



2.1.6 Instructions for use / Device Operating Manual(s)	Manufacturers must ensure that the information within the IFUs, especially related to intended purpose, indications, contra-indications, and other safety related information such as side effects, warnings is aligned with similar information from other sections such as risk management, clinical evaluation etc. IFUs must contain all the information required as per applicable requirements specified within GSPR 23. Manufacturers must as a minimum submit the English version at the time of application. (Manufacturer's processes and procedures for translation into other languages will be audited during BSI QMS audits)
2.1.7 Patient handbook	Some devices incorporate all the information relevant for the patient/user within the IFU itself. Some devices are accompanied by a patient handbook with additional instructions specific to the patient, for example with devices (or parts, components of the devices) that are patient operated. If the device is supplied with a patient handbook, this should be provided.
2.1.8 Physicians handbook	If a separate physicians' handbook is relevant for the device, this should be provided.
2.1.9 Implant card information	If applicable, the implant card and other information per Article 18 of MDR, and any additional information as specified in the MDCG guidance on Implant cards should be included. The location of the implant card within the device or system packaging should be clearly specified. The planned approach for translation of any information not in harmonized symbols should be described if applicable.
2.1.10 Electronic IFU (e-IFU) information (if applicable, and as per (EU) 207/2012)	If electronic IFU will be utilised, ensure compliance has been clearly outlined and evidence included to demonstrate compliance with all relevant aspects of Regulation 207/2012.
2.1.11 Copies of promotional materials (that mention that the device fulfils the requirements of CE marking) including any that make specific claims related to the device	Only marketing literature that mention that the device fulfils the requirements of CE marking or includes the CE mark itself is required to be provided. Supporting evidence should be provided in the relevant pre-clinical and clinical sections to substantiate any claims made in the labelling or marketing literature.
2.1.12 URL of the website where the IFU (and any other labelling information as relevant) will be made available as per GSPR 23.1	GSPR 23.1 requires that information related to identification, and safety and performance of the device shall be made available and kept up to date on the manufacturer's website if the manufacturer has a website. The URL of the website where such information will be made available should be included.
3. Design and Manufacturing Information	
3.1 Design Stages	

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BSI Class IIb 심사를 의한 BSI 절차에 맞는 MDR CE 인증 컨설팅 제공: iChopper

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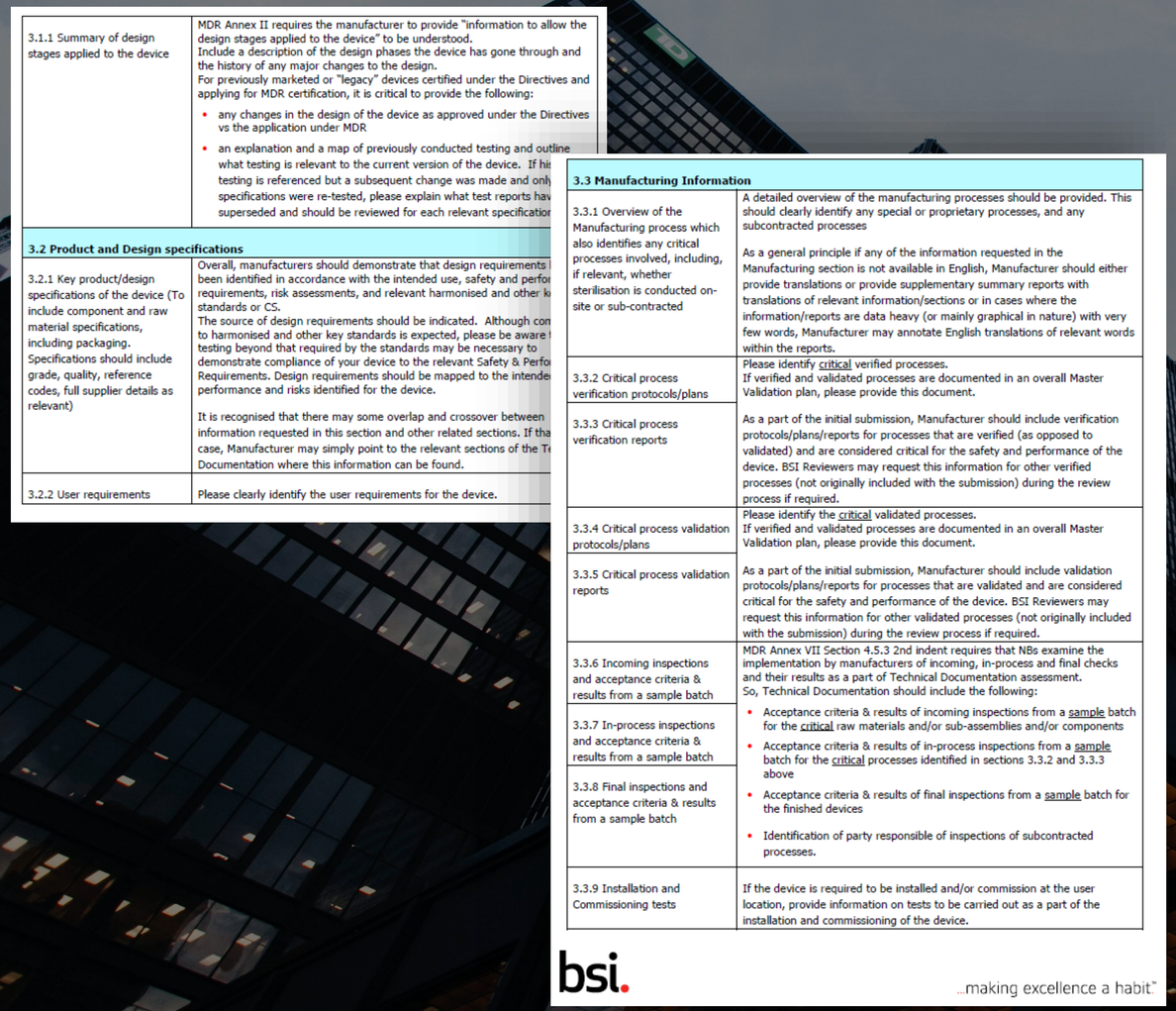
MDR 심사 보완요청 1차, 2차, 3차 라운드 대응

KBIO Solutions

MDR 컨설팅 진행



3.1.1 Summary of design stages applied to the device	MDR Annex II requires the manufacturer to provide "information to allow the design stages applied to the device" to be understood. Include a description of the design phases the device has gone through and the history of any major changes to the design. For previously marketed or "legacy" devices certified under the Directives and applying for MDR certification, it is critical to provide the following: • any changes in the design of the device as approved under the Directives vs the application under MDR • an explanation and a map of previously conducted testing and outline what testing is relevant to the current version of the device. If his testing is referenced but a subsequent change was made and only specifications were re-tested, please explain what test reports hav superseded and should be reviewed for each relevant specificatior
3.2 Product and Design specifications	
3.2.1 Key product/design specifications of the device (To include component and raw material specifications, including packaging. Specifications should include grade, quality, reference codes, full supplier details as relevant)	Overall, manufacturers should demonstrate that design requirements been identified in accordance with the intended use, safety and perfo requirements, risk assessments, and relevant harmonised and other k standards or CS. The source of design requirements should be indicated. Although con to harmonised and other key standards is expected, please be aware testing beyond that required by the standards may be necessary to demonstrate compliance of your device to the relevant Safety & Perfo Requirements. Design requirements should be mapped to the intende performance and risks identified for the device. It is recognised that there may some overlap and crossover between information requested in this section and other related sections. If tha case, Manufacturer may simply point to the relevant sections of the Te Documentation where this information can be found.
3.2.2 User requirements	Please clearly identify the user requirements for the device.

3.3 Manufacturing Information	
3.3.1 Overview of the Manufacturing process which also identifies any critical processes involved, including, if relevant, whether sterilisation is conducted on-site or sub-contracted	A detailed overview of the manufacturing processes should be provided. This should clearly identify any special or proprietary processes, and any subcontracted processes As a general principle if any of the information requested in the Manufacturing section is not available in English, Manufacturer should either provide translations or provide supplementary summary reports with translations of relevant information/sections or in cases where the information/reports are data heavy (or mainly graphical in nature) with very few words, Manufacturer may annotate English translations of relevant words within the reports.
3.3.2 Critical process verification protocols/plans	Please identify critical verified processes. If verified and validated processes are documented in an overall Master Validation plan, please provide this document.
3.3.3 Critical process verification reports	As a part of the initial submission, Manufacturer should include verification protocols/plans/reports for processes that are verified (as opposed to validated) and are considered critical for the safety and performance of the device. BSI Reviewers may request this information for other verified processes (not originally included with the submission) during the review process if required.
3.3.4 Critical process validation protocols/plans	Please identify the critical validated processes. If verified and validated processes are documented in an overall Master Validation plan, please provide this document.
3.3.5 Critical process validation reports	As a part of the initial submission, Manufacturer should include validation protocols/plans/reports for processes that are validated and are considered critical for the safety and performance of the device. BSI Reviewers may request this information for other validated processes (not originally included with the submission) during the review process if required.
3.3.6 Incoming inspections and acceptance criteria & results from a sample batch	MDR Annex VII Section 4.5.3 2nd indent requires that NBs examine the implementation by manufacturers of incoming, in-process and final checks and their results as a part of Technical Documentation assessment. So, Technical Documentation should include the following: • Acceptance criteria & results of incoming inspections from a sample batch for the critical raw materials and/or sub-assemblies and/or components • Acceptance criteria & results of in-process inspections from a sample batch for the critical processes identified in sections 3.3.2 and 3.3.3 above • Acceptance criteria & results of final inspections from a sample batch for the finished devices • Identification of party responsible of inspections of subcontracted processes.
3.3.7 In-process inspections and acceptance criteria & results from a sample batch	
3.3.8 Final inspections and acceptance criteria & results from a sample batch	
3.3.9 Installation and Commissioning tests	If the device is required to be installed and/or commission at the user location, provide information on tests to be carried out as a part of the installation and commissioning of the device.

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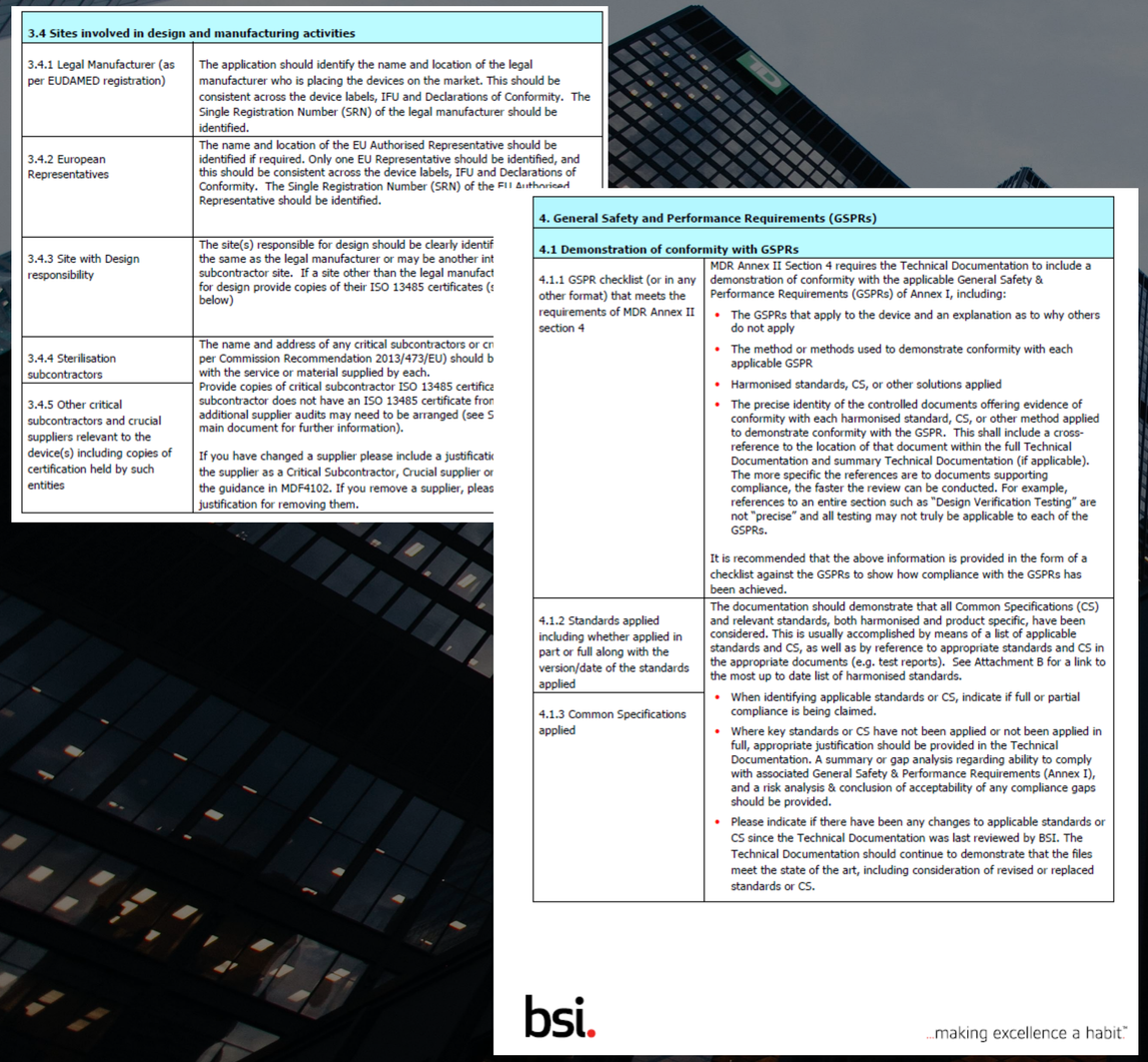

3.4 Sites involved in design and manufacturing activities	
3.4.1 Legal Manufacturer (as per EUDAMED registration)	The application should identify the name and location of the legal manufacturer who is placing the devices on the market. This should be consistent across the device labels, IFU and Declarations of Conformity. The Single Registration Number (SRN) of the legal manufacturer should be identified.
3.4.2 European Representatives	The name and location of the EU Authorised Representative should be identified if required. Only one EU Representative should be identified, and this should be consistent across the device labels, IFU and Declarations of Conformity. The Single Registration Number (SRN) of the EU Authorised Representative should be identified.
3.4.3 Site with Design responsibility	The site(s) responsible for design should be clearly identif the same as the legal manufacturer or may be another int subcontractor site. If a site other than the legal manufact for design provide copies of their ISO 13485 certificates (s below)
3.4.4 Sterilisation subcontractors	The name and address of any critical subcontractors or cr per Commission Recommendation 2013/473/EU) should b with the service or material supplied by each.
3.4.5 Other critical subcontractors and crucial suppliers relevant to the device(s) including copies of certification held by such entities	Provide copies of critical subcontractor ISO 13485 certifica subcontractor does not have an ISO 13485 certificate fron additional supplier audits may need to be arranged (see S main document for further information). If you have changed a supplier please include a justificati the supplier as a Critical Subcontractor, Crucial supplier or the guidance in MDF4102. If you remove a supplier, pleas justification for removing them.

4. General Safety and Performance Requirements (GSPRs)	
4.1 Demonstration of conformity with GSPRs	
4.1.1 GSPR checklist (or in any other format) that meets the requirements of MDR Annex II section 4	MDR Annex II Section 4 requires the Technical Documentation to include a demonstration of conformity with the applicable General Safety & Performance Requirements (GSPRs) of Annex I, including: • The GSPRs that apply to the device and an explanation as to why others do not apply • The method or methods used to demonstrate conformity with each applicable GSPR • Harmonised standards, CS, or other solutions applied • The precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS, or other method applied to demonstrate conformity with the GSPR. This shall include a cross-reference to the location of that document within the full Technical Documentation and summary Technical Documentation (if applicable). The more specific the references are to documents supporting compliance, the faster the review can be conducted. For example, references to an entire section such as "Design Verification Testing" are not "precise" and all testing may not truly be applicable to each of the GSPRs. It is recommended that the above information is provided in the form of a checklist against the GSPRs to show how compliance with the GSPRs has been achieved.
4.1.2 Standards applied including whether applied in part or full along with the version/date of the standards applied	The documentation should demonstrate that all Common Specifications (CS) and relevant standards, both harmonised and product specific, have been considered. This is usually accomplished by means of a list of applicable standards and CS, as well as by reference to appropriate standards and CS in the appropriate documents (e.g. test reports). See Attachment B for a link to the most up to date list of harmonised standards.
4.1.3 Common Specifications applied	• When identifying applicable standards or CS, indicate if full or partial compliance is being claimed. • Where key standards or CS have not been applied or not been applied in full, appropriate justification should be provided in the Technical Documentation. A summary or gap analysis regarding ability to comply with associated General Safety & Performance Requirements (Annex I), and a risk analysis & conclusion of acceptability of any compliance gaps should be provided. • Please indicate if there have been any changes to applicable standards or CS since the Technical Documentation was last reviewed by BSI. The Technical Documentation should continue to demonstrate that the files meet the state of the art, including consideration of revised or replaced standards or CS.

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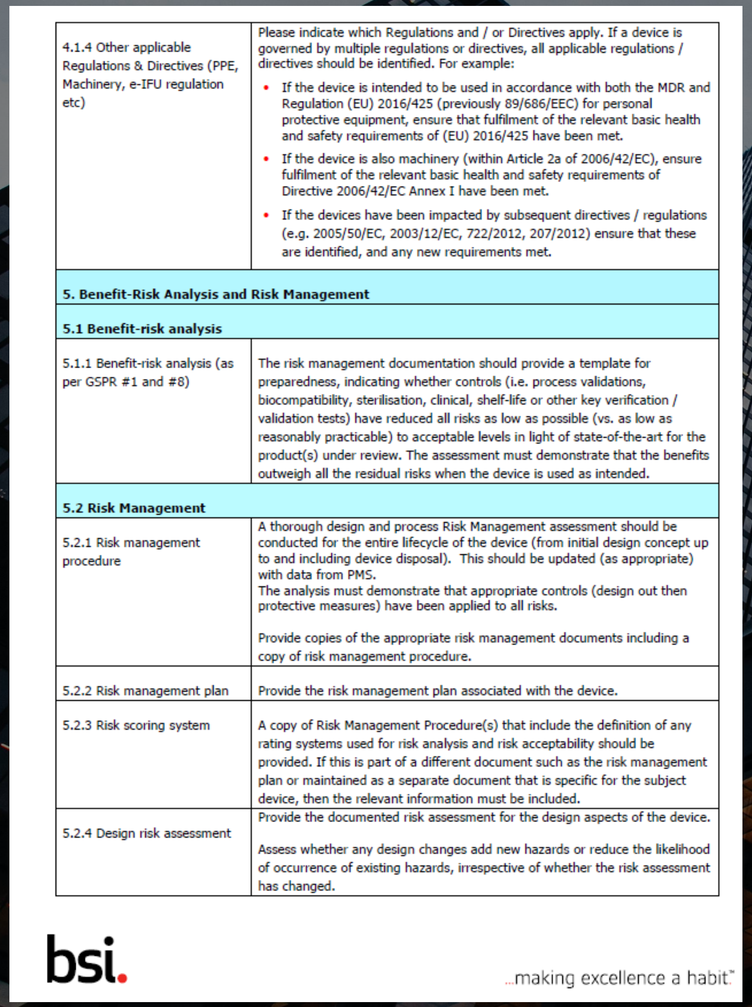

4.1.4 Other applicable Regulations & Directives (PPE, Machinery, e-IFU regulation etc)	Please indicate which Regulations and / or Directives apply. If a device is governed by multiple regulations or directives, all applicable regulations / directives should be identified. For example: • If the device is intended to be used in accordance with both the MDR and Regulation (EU) 2016/425 (previously 89/686/EEC) for personal protective equipment, ensure that fulfilment of the relevant basic health and safety requirements of (EU) 2016/425 have been met. • If the device is also machinery (within Article 2a of 2006/42/EC), ensure fulfilment of the relevant basic health and safety requirements of Directive 2006/42/EC Annex I have been met. • If the devices have been impacted by subsequent directives / regulations (e.g. 2005/50/EC, 2003/12/EC, 722/2012, 207/2012) ensure that these are identified, and any new requirements met.
5. Benefit-Risk Analysis and Risk Management	
5.1 Benefit-risk analysis	
5.1.1 Benefit-risk analysis (as per GSPR #1 and #8)	The risk management documentation should provide a template for preparedness, indicating whether controls (i.e. process validations, biocompatibility, sterilisation, clinical, shelf-life or other key verification / validation tests) have reduced all risks as low as possible (vs. as low as reasonably practicable) to acceptable levels in light of state-of-the-art for the product(s) under review. The assessment must demonstrate that the benefits outweigh all the residual risks when the device is used as intended.
5.2 Risk Management	
5.2.1 Risk management procedure	A thorough design and process Risk Management assessment should be conducted for the entire lifecycle of the device (from initial design concept up to and including device disposal). This should be updated (as appropriate) with data from PMS. The analysis must demonstrate that appropriate controls (design out then protective measures) have been applied to all risks. Provide copies of the appropriate risk management documents including a copy of risk management procedure.
5.2.2 Risk management plan	Provide the risk management plan associated with the device.
5.2.3 Risk scoring system	A copy of Risk Management Procedure(s) that include the definition of any rating systems used for risk analysis and risk acceptability should be provided. If this is part of a different document such as the risk management plan or maintained as a separate document that is specific for the subject device, then the relevant information must be included.
5.2.4 Design risk assessment	Provide the documented risk assessment for the design aspects of the device. Assess whether any design changes add new hazards or reduce the likelihood of occurrence of existing hazards, irrespective of whether the risk assessment has changed.

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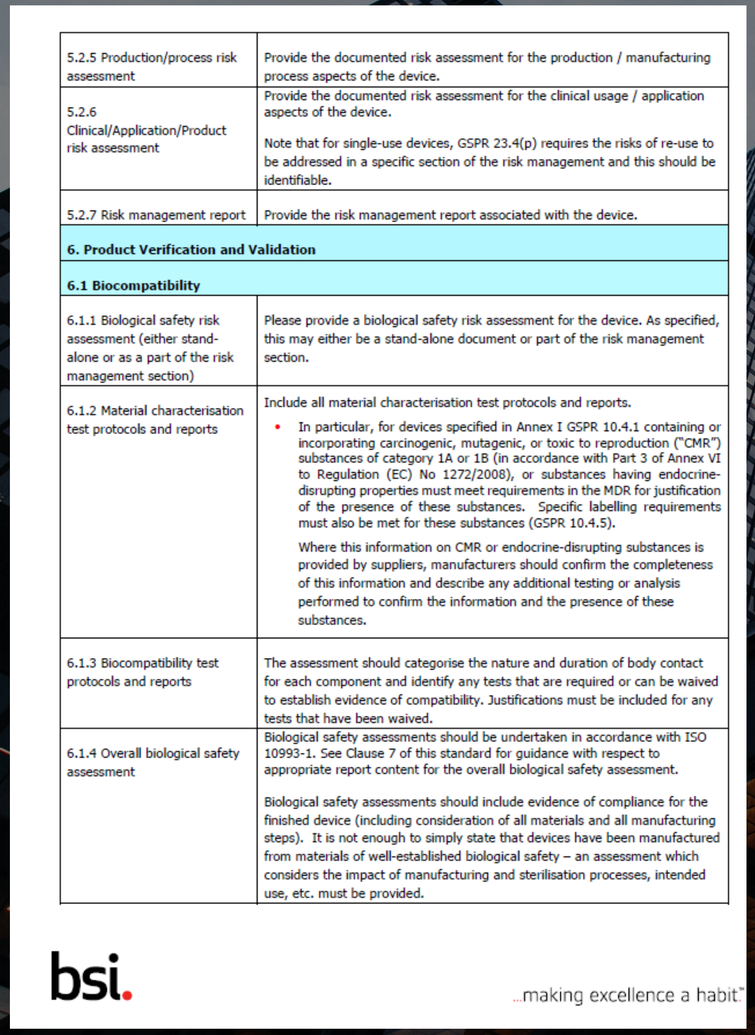

5.2.5 Production/process risk assessment	Provide the documented risk assessment for the production / manufacturing process aspects of the device.
5.2.6 Clinical/Application/Product risk assessment	Provide the documented risk assessment for the clinical usage / application aspects of the device. Note that for single-use devices, GSPR 23.4(p) requires the risks of re-use to be addressed in a specific section of the risk management and this should be identifiable.
5.2.7 Risk management report	Provide the risk management report associated with the device.
6. Product Verification and Validation	
6.1 Biocompatibility	
6.1.1 Biological safety risk assessment (either stand-alone or as a part of the risk management section)	Please provide a biological safety risk assessment for the device. As specified, this may either be a stand-alone document or part of the risk management section.
6.1.2 Material characterisation test protocols and reports	Include all material characterisation test protocols and reports. • In particular, for devices specified in Annex I GSPR 10.4.1 containing or incorporating carcinogenic, mutagenic, or toxic to reproduction ("CMR") substances of category 1A or 1B (in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008), or substances having endocrine-disrupting properties must meet requirements in the MDR for justification of the presence of these substances. Specific labelling requirements must also be met for these substances (GSPR 10.4.5). Where this information on CMR or endocrine-disrupting substances is provided by suppliers, manufacturers should confirm the completeness of this information and describe any additional testing or analysis performed to confirm the information and the presence of these substances.
6.1.3 Biocompatibility test protocols and reports	The assessment should categorise the nature and duration of body contact for each component and identify any tests that are required or can be waived to establish evidence of compatibility. Justifications must be included for any tests that have been waived.
6.1.4 Overall biological safety assessment	Biological safety assessments should be undertaken in accordance with ISO 10993-1. See Clause 7 of this standard for guidance with respect to appropriate report content for the overall biological safety assessment. Biological safety assessments should include evidence of compliance for the finished device (including consideration of all materials and all manufacturing steps). It is not enough to simply state that devices have been manufactured from materials of well-established biological safety – an assessment which considers the impact of manufacturing and sterilisation processes, intended use, etc. must be provided.

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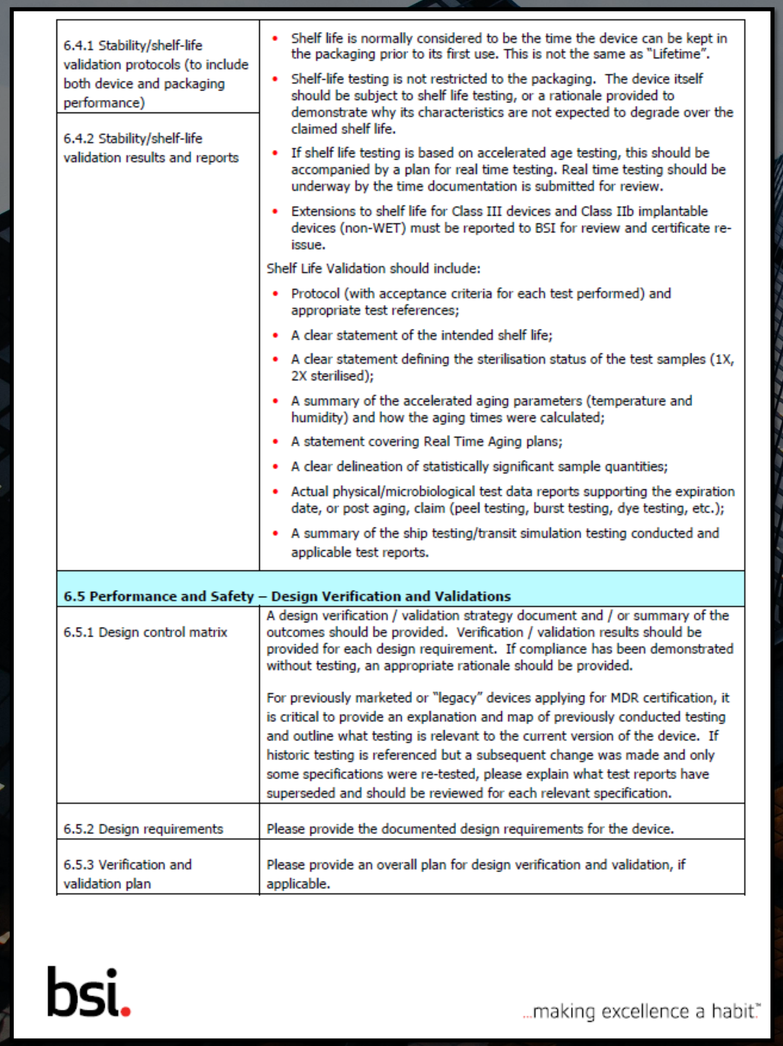

6.4.1 Stability/shelf-life validation protocols (to include both device and packaging performance)	• Shelf life is normally considered to be the time the device can be kept in the packaging prior to its first use. This is not the same as "Lifetime". • Shelf-life testing is not restricted to the packaging. The device itself should be subject to shelf life testing, or a rationale provided to demonstrate why its characteristics are not expected to degrade over the claimed shelf life. • If shelf life testing is based on accelerated age testing, this should be accompanied by a plan for real time testing. Real time testing should be underway by the time documentation is submitted for review. • Extensions to shelf life for Class III devices and Class IIb implantable devices (non-WET) must be reported to BSI for review and certificate re-issue. Shelf Life Validation should include: • Protocol (with acceptance criteria for each test performed) and appropriate test references; • A clear statement of the intended shelf life; • A clear statement defining the sterilisation status of the test samples (1X, 2X sterilised); • A summary of the accelerated aging parameters (temperature and humidity) and how the aging times were calculated; • A statement covering Real Time Aging plans; • A clear delineation of statistically significant sample quantities; • Actual physical/microbiological test data reports supporting the expiration date, or post aging, claim (peel testing, burst testing, dye testing, etc.); • A summary of the ship testing/transit simulation testing conducted and applicable test reports.
6.4.2 Stability/shelf-life validation results and reports	
6.5 Performance and Safety – Design Verification and Validations	
6.5.1 Design control matrix	A design verification / validation strategy document and / or summary of the outcomes should be provided. Verification / validation results should be provided for each design requirement. If compliance has been demonstrated without testing, an appropriate rationale should be provided. For previously marketed or "legacy" devices applying for MDR certification, it is critical to provide an explanation and map of previously conducted testing and outline what testing is relevant to the current version of the device. If historic testing is referenced but a subsequent change was made and only some specifications were re-tested, please explain what test reports have superseded and should be reviewed for each relevant specification.
6.5.2 Design requirements	Please provide the documented design requirements for the device.
6.5.3 Verification and validation plan	Please provide an overall plan for design verification and validation, if applicable.

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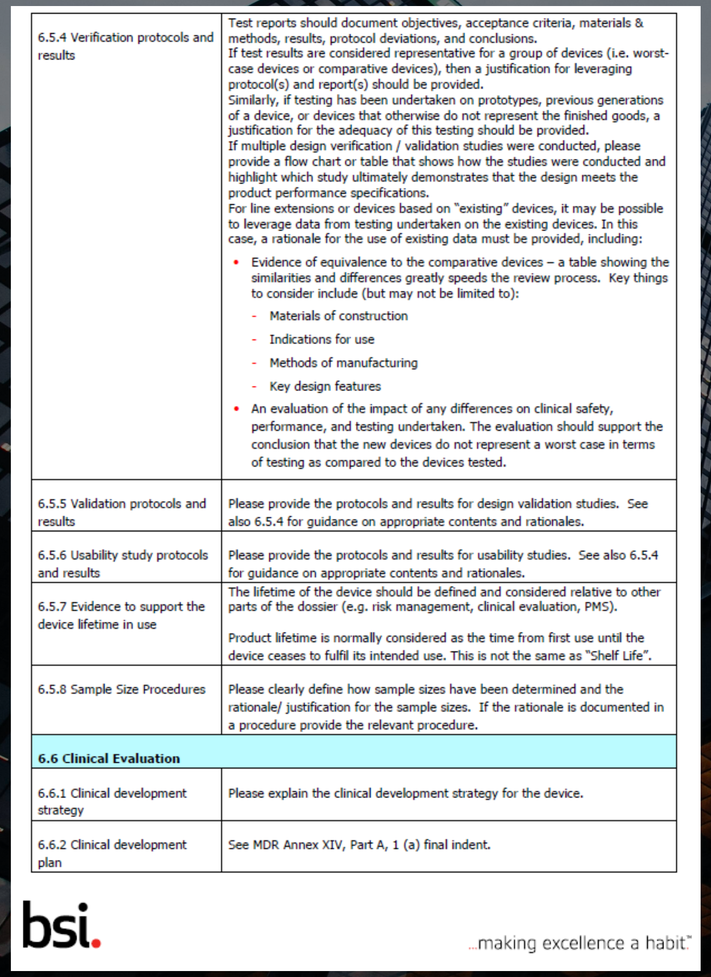

6.5.4 Verification protocols and results	Test reports should document objectives, acceptance criteria, materials & methods, results, protocol deviations, and conclusions. If test results are considered representative for a group of devices (i.e. worst-case devices or comparative devices), then a justification for leveraging protocol(s) and report(s) should be provided. Similarly, if testing has been undertaken on prototypes, previous generations of a device, or devices that otherwise do not represent the finished goods, a justification for the adequacy of this testing should be provided. If multiple design verification / validation studies were conducted, please provide a flow chart or table that shows how the studies were conducted and highlight which study ultimately demonstrates that the design meets the product performance specifications. For line extensions or devices based on "existing" devices, it may be possible to leverage data from testing undertaken on the existing devices. In this case, a rationale for the use of existing data must be provided, including: • Evidence of equivalence to the comparative devices – a table showing the similarities and differences greatly speeds the review process. Key things to consider include (but may not be limited to): - Materials of construction - Indications for use - Methods of manufacturing - Key design features • An evaluation of the impact of any differences on clinical safety, performance, and testing undertaken. The evaluation should support the conclusion that the new devices do not represent a worst case in terms of testing as compared to the devices tested.
6.5.5 Validation protocols and results	Please provide the protocols and results for design validation studies. See also 6.5.4 for guidance on appropriate contents and rationales.
6.5.6 Usability study protocols and results	Please provide the protocols and results for usability studies. See also 6.5.4 for guidance on appropriate contents and rationales.
6.5.7 Evidence to support the device lifetime in use	The lifetime of the device should be defined and considered relative to other parts of the dossier (e.g. risk management, clinical evaluation, PMS). Product lifetime is normally considered as the time from first use until the device ceases to fulfil its intended use. This is not the same as "Shelf Life".
6.5.8 Sample Size Procedures	Please clearly define how sample sizes have been determined and the rationale/ justification for the sample sizes. If the rationale is documented in a procedure provide the relevant procedure.
6.6 Clinical Evaluation	
6.6.1 Clinical development strategy	Please explain the clinical development strategy for the device.
6.6.2 Clinical development plan	See MDR Annex XIV, Part A, 1 (a) final indent.

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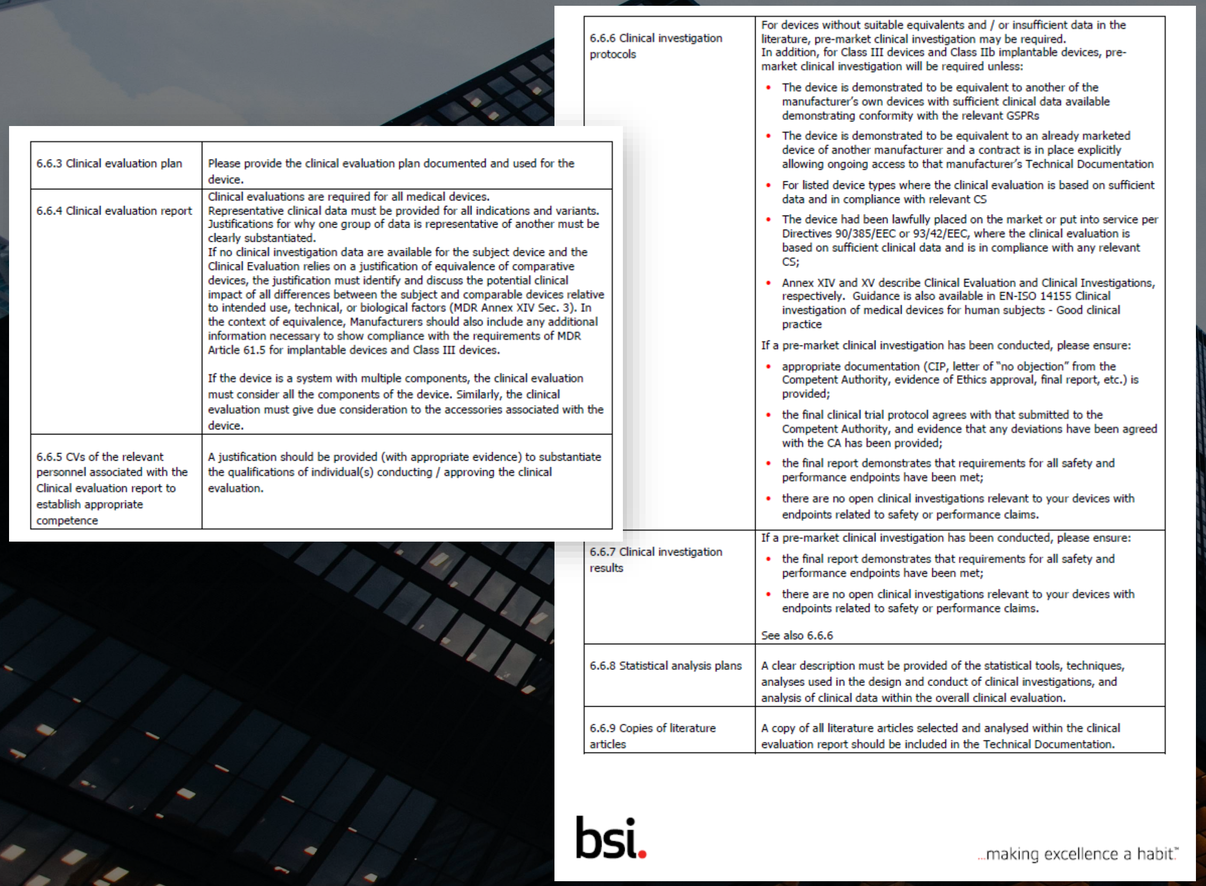

6.6.3 Clinical evaluation plan	Please provide the clinical evaluation plan documented and used for the device.
6.6.4 Clinical evaluation report	Clinical evaluations are required for all medical devices. Representative clinical data must be provided for all indications and variants. Justifications for why one group of data is representative of another must be clearly substantiated. If no clinical investigation data are available for the subject device and the Clinical Evaluation relies on a justification of equivalence of comparative devices, the justification must identify and discuss the potential clinical impact of all differences between the subject and comparable devices relative to intended use, technical, or biological factors (MDR Annex XIV Sec. 3). In the context of equivalence, Manufacturers should also include any additional information necessary to show compliance with the requirements of MDR Article 61.5 for implantable devices and Class III devices. If the device is a system with multiple components, the clinical evaluation must consider all the components of the device. Similarly, the clinical evaluation must give due consideration to the accessories associated with the device.
6.6.5 CVs of the relevant personnel associated with the Clinical evaluation report to establish appropriate competence	A justification should be provided (with appropriate evidence) to substantiate the qualifications of individual(s) conducting / approving the clinical evaluation.
6.6.6 Clinical investigation protocols	For devices without suitable equivalents and / or insufficient data in the literature, pre-market clinical investigation may be required. In addition, for Class III devices and Class IIb implantable devices, pre-market clinical investigation will be required unless: • The device is demonstrated to be equivalent to another of the manufacturer's own devices with sufficient clinical data available demonstrating conformity with the relevant GSPRs • The device is demonstrated to be equivalent to an already marketed device of another manufacturer and a contract is in place explicitly allowing ongoing access to that manufacturer's Technical Documentation • For listed device types where the clinical evaluation is based on sufficient data and in compliance with relevant CS • The device had been lawfully placed on the market or put into service per Directives 90/385/EEC or 93/42/EEC, where the clinical evaluation is based on sufficient clinical data and is in compliance with any relevant CS; • Annex XIV and XV describe Clinical Evaluation and Clinical Investigations, respectively. Guidance is also available in EN-ISO 14155 Clinical investigation of medical devices for human subjects - Good clinical practice If a pre-market clinical investigation has been conducted, please ensure: • appropriate documentation (CIP, letter of "no objection" from the Competent Authority, evidence of Ethics approval, final report, etc.) is provided; • the final clinical trial protocol agrees with that submitted to the Competent Authority, and evidence that any deviations have been agreed with the CA has been provided; • the final report demonstrates that requirements for all safety and performance endpoints have been met; • there are no open clinical investigations relevant to your devices with endpoints related to safety or performance claims.
6.6.7 Clinical investigation results	If a pre-market clinical investigation has been conducted, please ensure: • the final report demonstrates that requirements for all safety and performance endpoints have been met; • there are no open clinical investigations relevant to your devices with endpoints related to safety or performance claims. See also 6.6.6
6.6.8 Statistical analysis plans	A clear description must be provided of the statistical tools, techniques, analyses used in the design and conduct of clinical investigations, and analysis of clinical data within the overall clinical evaluation.
6.6.9 Copies of literature articles	A copy of all literature articles selected and analysed within the clinical evaluation report should be included in the Technical Documentation.

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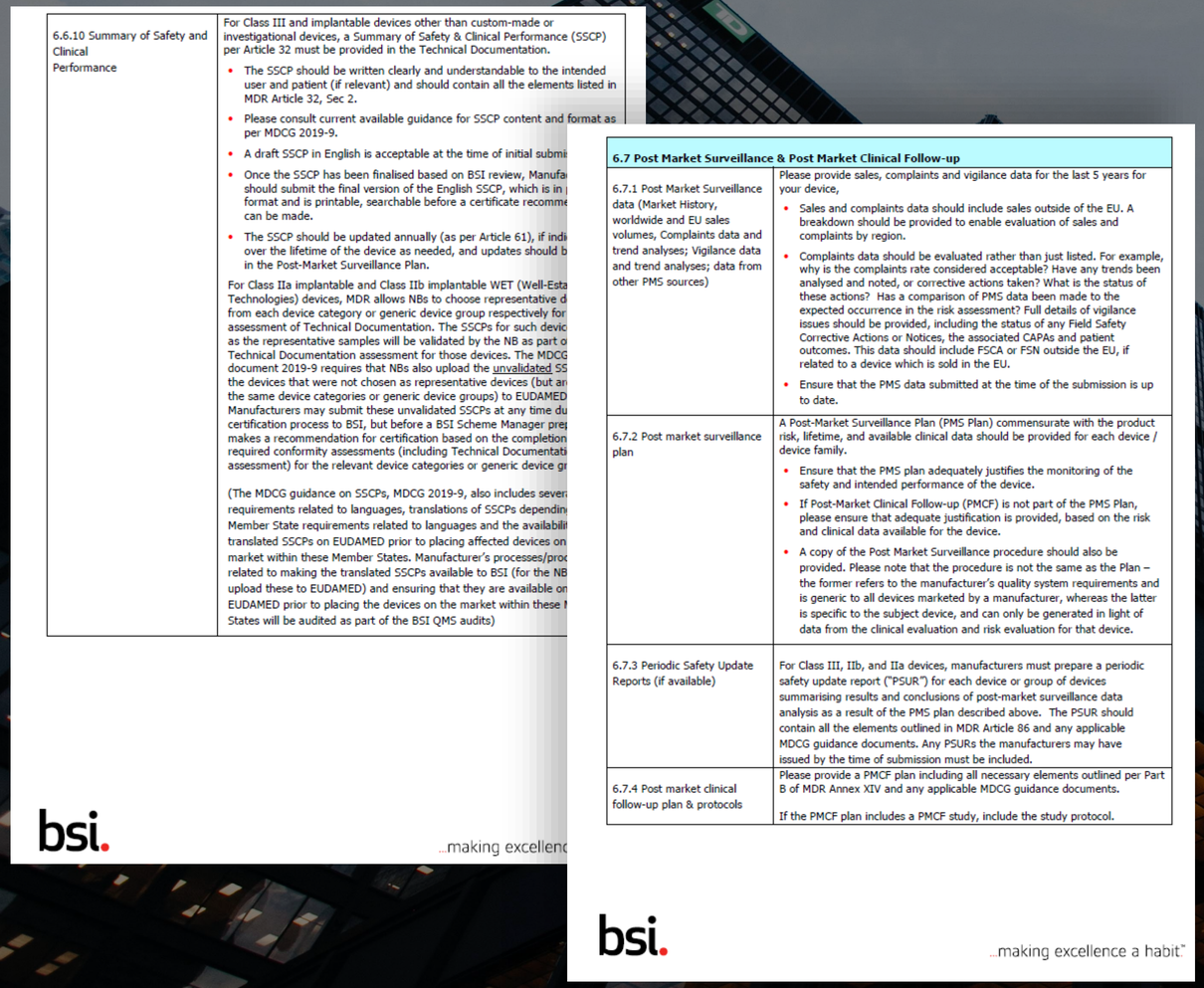

6.6.10 Summary of Safety and Clinical Performance	For Class III and implantable devices other than custom-made or investigational devices, a Summary of Safety & Clinical Performance (SSCP) per Article 32 must be provided in the Technical Documentation. • The SSCP should be written clearly and understandable to the intended user and patient (if relevant) and should contain all the elements listed in MDR Article 32, Sec 2. • Please consult current available guidance for SSCP content and format as per MDCG 2019-9. • A draft SSCP in English is acceptable at the time of initial submi • Once the SSCP has been finalised based on BSI review, Manufa should submit the final version of the English SSCP, which is in format and is printable, searchable before a certificate recomme can be made. • The SSCP should be updated annually (as per Article 61), if indi over the lifetime of the device as needed, and updates should b in the Post-Market Surveillance Plan. For Class IIa implantable and Class IIb implantable WET (Well-Esta Technologies) devices, MDR allows NBs to choose representative d from each device category or generic device group respectively for assessment of Technical Documentation. The SSCPs for such devic as the representative samples will be validated by the NB as part o Technical Documentation assessment for those devices. The MDCG document 2019-9 requires that NBs also upload the unvalidated SS the devices that were not chosen as representative devices (but ar the same device categories or generic device groups) to EUDAMED Manufacturers may submit these unvalidated SSCPs at any time du certification process to BSI, but before a BSI Scheme Manager prep makes a recommendation for certification based on the completion required conformity assessments (including Technical Documentati assessment) for the relevant device categories or generic device gr (The MDCG guidance on SSCPs, MDCG 2019-9, also includes sever requirements related to languages, translations of SSCPs dependin Member State requirements related to languages and the availabili translated SSCPs on EUDAMED prior to placing affected devices on market within these Member States. Manufacturer's processes/proc related to making the translated SSCPs available to BSI (for the NB upload these to EUDAMED) and ensuring that they are available on EUDAMED prior to placing the devices on the market within these M States will be audited as part of the BSI QMS audits)

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6.7 Post Market Surveillance & Post Market Clinical Follow-up	
6.7.1 Post Market Surveillance data (Market History, worldwide and EU sales volumes, Complaints data and trend analyses; Vigilance data and trend analyses; data from other PMS sources)	Please provide sales, complaints and vigilance data for the last 5 years for your device, • Sales and complaints data should include sales outside of the EU. A breakdown should be provided to enable evaluation of sales and complaints by region. • Complaints data should be evaluated rather than just listed. For example, why is the complaints rate considered acceptable? Have any trends been analysed and noted, or corrective actions taken? What is the status of these actions? Has a comparison of PMS data been made to the expected occurrence in the risk assessment? Full details of vigilance issues should be provided, including the status of any Field Safety Corrective Actions or Notices, the associated CAPAs and patient outcomes. This data should include FSCA or FSN outside the EU, if related to a device which is sold in the EU. • Ensure that the PMS data submitted at the time of the submission is up to date.
6.7.2 Post market surveillance plan	A Post-Market Surveillance Plan (PMS Plan) commensurate with the product risk, lifetime, and available clinical data should be provided for each device / device family. • Ensure that the PMS plan adequately justifies the monitoring of the safety and intended performance of the device. • If Post-Market Clinical Follow-up (PMCF) is not part of the PMS Plan, please ensure that adequate justification is provided, based on the risk and clinical data available for the device. • A copy of the Post Market Surveillance procedure should also be provided. Please note that the procedure is not the same as the Plan – the former refers to the manufacturer's quality system requirements and is generic to all devices marketed by a manufacturer, whereas the latter is specific to the subject device, and can only be generated in light of data from the clinical evaluation and risk evaluation for that device.
6.7.3 Periodic Safety Update Reports (if available)	For Class III, IIb, and IIa devices, manufacturers must prepare a periodic safety update report ("PSUR") for each device or group of devices summarising results and conclusions of post-market surveillance data analysis as a result of the PMS plan described above. The PSUR should contain all the elements outlined in MDR Article 86 and any applicable MDCG guidance documents. Any PSURs the manufacturers may have issued by the time of submission must be included.
6.7.4 Post market clinical follow-up plan & protocols	Please provide a PMCF plan including all necessary elements outlined per Part B of MDR Annex XIV and any applicable MDCG guidance documents. If the PMCF plan includes a PMCF study, include the study protocol.

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- Technical Documentation
- GSPR
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MDR 심사 보완요청 1차, 2차, 3차 라운드 대응

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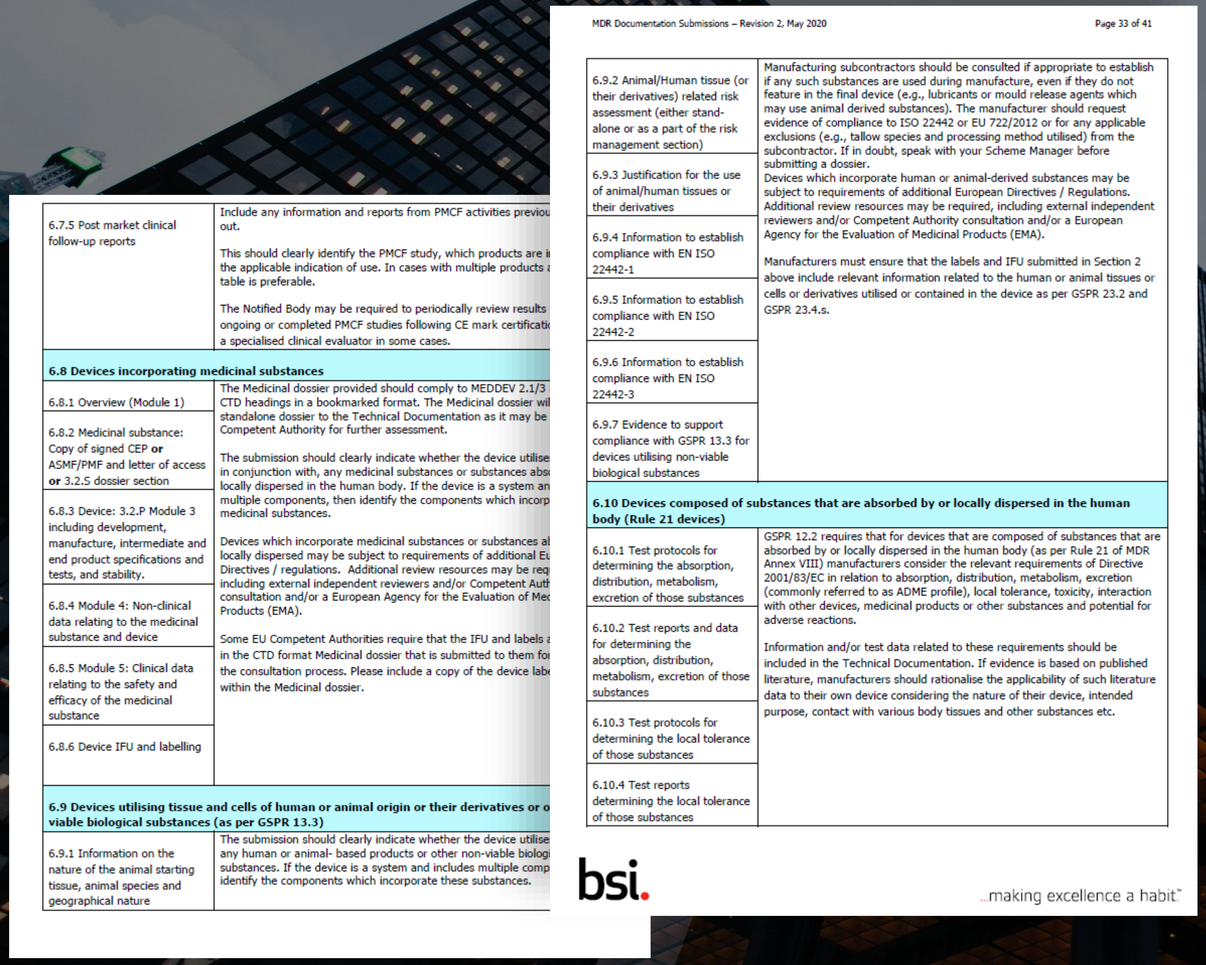
MDR 컨설팅 진행



6.7.5 Post market clinical follow-up reports	Include any information and reports from PMCF activities previou out. This should clearly identify the PMCF study, which products are i the applicable indication of use. In cases with multiple products a table is preferable. The Notified Body may be required to periodically review results ongoing or completed PMCF studies following CE mark certificati a specialised clinical evaluator in some cases.
6.8 Devices incorporating medicinal substances	
6.8.1 Overview (Module 1)	The Medicinal dossier provided should comply to MEDDEV 2.1/3 CTD headings in a bookmarked format. The Medicinal dossier wil standalone dossier to the Technical Documentation as it may be Competent Authority for further assessment. The submission should clearly indicate whether the device utilise in conjunction with, any medicinal substances or substances abs locally dispersed in the human body. If the device is a system an multiple components, then identify the components which incorp medicinal substances. Devices which incorporate medicinal substances or substances al locally dispersed may be subject to requirements of additional Eu Directives / regulations. Additional review resources may be req including external independent reviewers and/or Competent Auth consultation and/or a European Agency for the Evaluation of Me Products (EMA). Some EU Competent Authorities require that the IFU and labels a in the CTD format Medicinal dossier that is submitted to them fo the consultation process. Please include a copy of the device lab within the Medicinal dossier.
6.8.2 Medicinal substance: Copy of signed CEP **or** ASMF/PMF and letter of access **or** 3.2.S dossier section	
6.8.3 Device: 3.2.P Module 3 including development, manufacture, intermediate and end product specifications and tests, and stability.	
6.8.4 Module 4: Non-clinical data relating to the medicinal substance and device	
6.8.5 Module 5: Clinical data relating to the safety and efficacy of the medicinal substance	
6.8.6 Device IFU and labelling	
6.9 Devices utilising tissue and cells of human or animal origin or their derivatives or o viable biological substances (as per GSPR 13.3)	
6.9.1 Information on the nature of the animal starting tissue, animal species and geographical nature	The submission should clearly indicate whether the device utilise any human or animal- based products or other non-viable biologi substances. If the device is a system and includes multiple comp identify the components which incorporate these substances.

6.9.2 Animal/Human tissue (or their derivatives) related risk assessment (either stand-alone or as a part of the risk management section)	Manufacturing subcontractors should be consulted if appropriate to establish if any such substances are used during manufacture, even if they do not feature in the final device (e.g., lubricants or mould release agents which may use animal derived substances). The manufacturer should request evidence of compliance to ISO 22442 or EU 722/2012 or for any applicable exclusions (e.g., tallow species and processing method utilised) from the subcontractor. If in doubt, speak with your Scheme Manager before submitting a dossier. Devices which incorporate human or animal-derived substances may be subject to requirements of additional European Directives / Regulations. Additional review resources may be required, including external independent reviewers and/or Competent Authority consultation and/or a European Agency for the Evaluation of Medicinal Products (EMA). Manufacturers must ensure that the labels and IFU submitted in Section 2 above include relevant information related to the human or animal tissues or cells or derivatives utilised or contained in the device as per GSPR 23.2 and GSPR 23.4.s.
6.9.3 Justification for the use of animal/human tissues or their derivatives	
6.9.4 Information to establish compliance with EN ISO 22442-1	
6.9.5 Information to establish compliance with EN ISO 22442-2	
6.9.6 Information to establish compliance with EN ISO 22442-3	
6.9.7 Evidence to support compliance with GSPR 13.3 for devices utilising non-viable biological substances	
6.10 Devices composed of substances that are absorbed by or locally dispersed in the human body (Rule 21 devices)	
6.10.1 Test protocols for determining the absorption, distribution, metabolism, excretion of those substances	GSPR 12.2 requires that for devices that are composed of substances that are absorbed by or locally dispersed in the human body (as per Rule 21 of MDR Annex VIII) manufacturers consider the relevant requirements of Directive 2001/83/EC in relation to absorption, distribution, metabolism, excretion (commonly referred to as ADME profile), local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions. Information and/or test data related to these requirements should be included in the Technical Documentation. If evidence is based on published literature, manufacturers should rationalise the applicability of such literature data to their own device considering the nature of their device, intended purpose, contact with various body tissues and other substances etc.
6.10.2 Test reports and data for determining the absorption, distribution, metabolism, excretion of those substances	
6.10.3 Test protocols for determining the local tolerance of those substances	
6.10.4 Test reports determining the local tolerance of those substances	

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MDR 심사 보완요청 1차, 2차, 3차 라운드 대응

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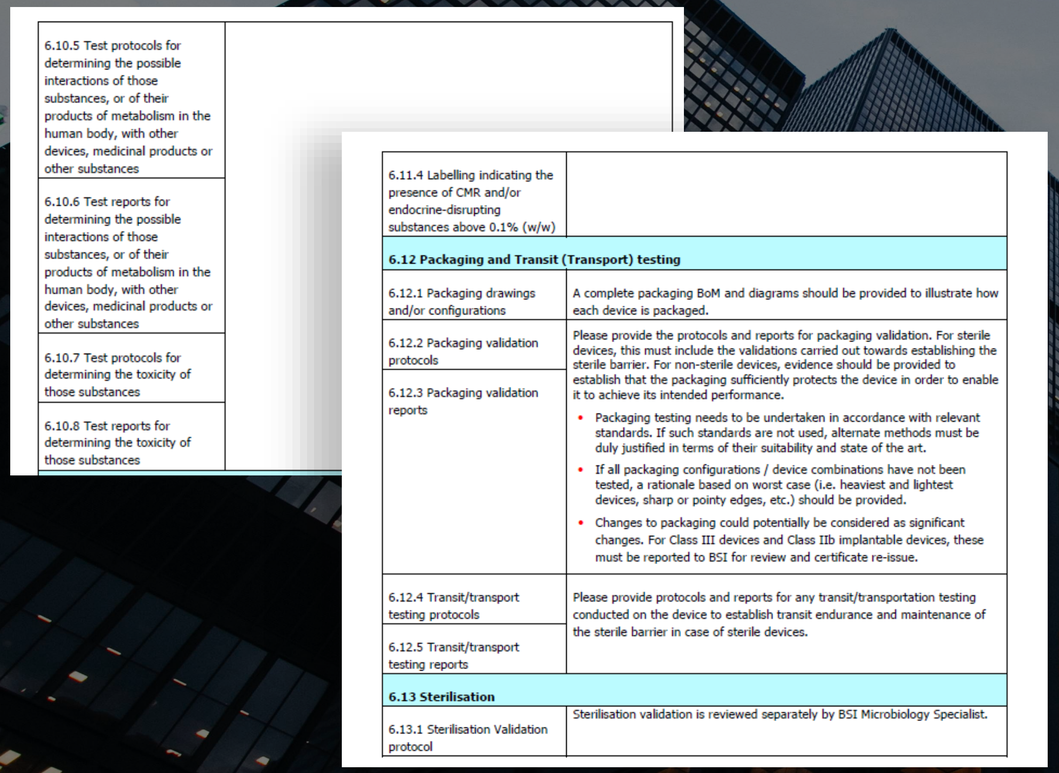
MDR 컨설팅 진행



6.10.5 Test protocols for determining the possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances	
6.10.6 Test reports for determining the possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances	
6.10.7 Test protocols for determining the toxicity of those substances	
6.10.8 Test reports for determining the toxicity of those substances	

6.11.4 Labelling indicating the presence of CMR and/or endocrine-disrupting substances above 0.1% (w/w)	
6.12 Packaging and Transit (Transport) testing	
6.12.1 Packaging drawings and/or configurations	A complete packaging BoM and diagrams should be provided to illustrate how each device is packaged.
6.12.2 Packaging validation protocols	Please provide the protocols and reports for packaging validation. For sterile devices, this must include the validations carried out towards establishing the sterile barrier. For non-sterile devices, evidence should be provided to establish that the packaging sufficiently protects the device in order to enable it to achieve its intended performance. • Packaging testing needs to be undertaken in accordance with relevant standards. If such standards are not used, alternate methods must be duly justified in terms of their suitability and state of the art. • If all packaging configurations / device combinations have not been tested, a rationale based on worst case (i.e. heaviest and lightest devices, sharp or pointy edges, etc.) should be provided. • Changes to packaging could potentially be considered as significant changes. For Class III devices and Class IIb implantable devices, these must be reported to BSI for review and certificate re-issue.
6.12.3 Packaging validation reports	
6.12.4 Transit/transport testing protocols	Please provide protocols and reports for any transit/transportation testing conducted on the device to establish transit endurance and maintenance of the sterile barrier in case of sterile devices.
6.12.5 Transit/transport testing reports	
6.13 Sterilisation	
6.13.1 Sterilisation Validation protocol	Sterilisation validation is reviewed separately by BSI Microbiology Specialist.

BSI Class IIb 심사를 의한 BSI 절차에 맞는 MDR CE 인증 컨설팅 제공: iChopper

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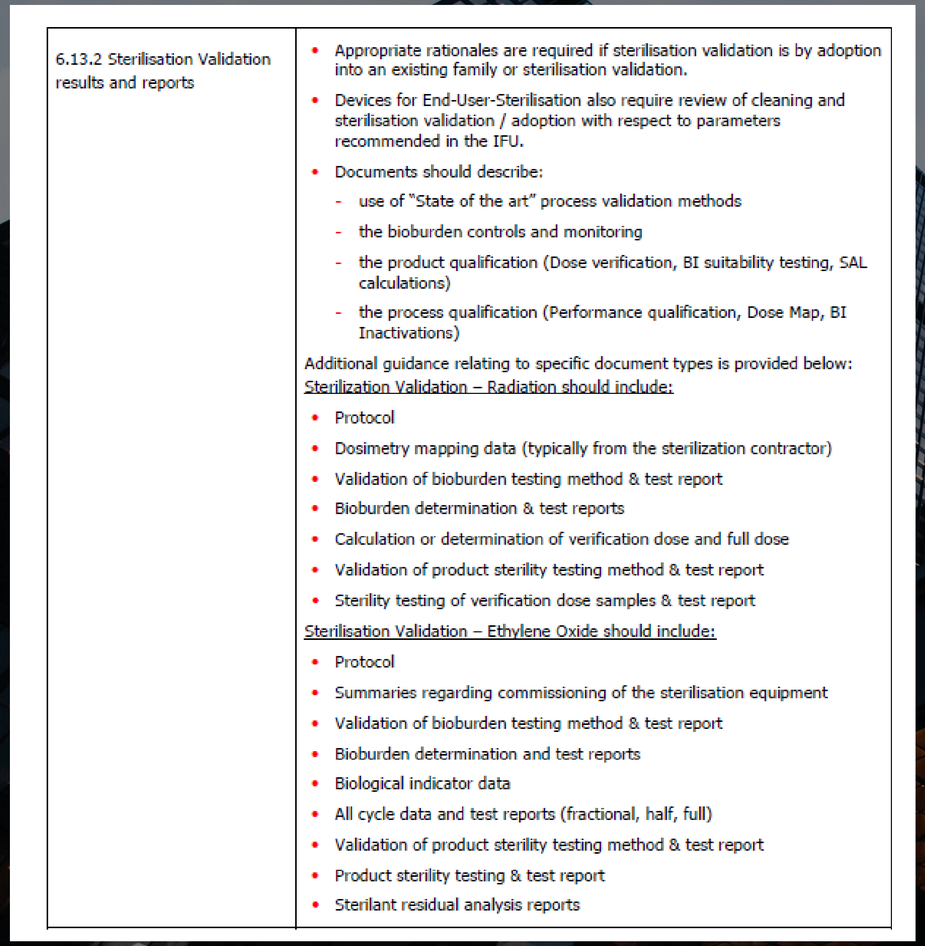
MDR 컨설팅 진행



6.13.2 Sterilisation Validation results and reports	• Appropriate rationales are required if sterilisation validation is by adoption into an existing family or sterilisation validation. • Devices for End-User-Sterilisation also require review of cleaning and sterilisation validation / adoption with respect to parameters recommended in the IFU. • Documents should describe: - use of "State of the art" process validation methods - the bioburden controls and monitoring - the product qualification (Dose verification, BI suitability testing, SAL calculations) - the process qualification (Performance qualification, Dose Map, BI Inactivations) Additional guidance relating to specific document types is provided below: Sterilization Validation – Radiation should include: • Protocol • Dosimetry mapping data (typically from the sterilization contractor) • Validation of bioburden testing method & test report • Bioburden determination & test reports • Calculation or determination of verification dose and full dose • Validation of product sterility testing method & test report • Sterility testing of verification dose samples & test report Sterilisation Validation – Ethylene Oxide should include: • Protocol • Summaries regarding commissioning of the sterilisation equipment • Validation of bioburden testing method & test report • Bioburden determination and test reports • Biological indicator data • All cycle data and test reports (fractional, half, full) • Validation of product sterility testing method & test report • Product sterility testing & test report • Sterilant residual analysis reports

BSI Class IIb 심사를 의한 BSI 절차에 맞는 MDR CE 인증 컨설팅 제공: iChopper

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대조비교 RCT 임상시험

다기관 무작위배정 비열등성 전향적 확증 임상

임상 프로토콜 설계, 작성	식약처 임상시험 승인 심사 수행	3개 임상병원 IRB 심사진행	임상모집 마지막 환자 Follow up	임상데이터 결과분석

KBIO Solutions

전향적 RCT 임상시험

식품의약품안전처에 임상시험계획 승인 제출할 파일 준비
- 임상시험계획서 프로토콜 설계, 작성: 1차 유효성 평가변수: 4분 지혈성공률, 2차 유효성 평가: 2분지혈, 10분지혈, 재출혈률
-환자동의서 ICF작성
-식약처 접수 문서 작성
3개병원 IRB 제출할 파일 준비

간절제술 Floseal 지혈률 83% 논문 결과 대비한 비열등성 임상시험으로 계획

앤씨비아이티 130명 확증 임상평가 완료후
신속한 데이타 관리/통계분석/결과보고서 작성 진행

상기 타임라인은 식약처 승인시점및 환자모집속도에 따라
변동될 수 있습니다.

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5-B

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전향적 비교 임상시험

전향적 비교 임상시험:

- 식약처, IRB심사진행
- 임상시험 평가
- 임상 모니터링
- 임상 데이타수집
- 통계분석
- 결과보고서 완성

4 2023년 9월 첫환자 모집
2024년 6월-7월: 마지막 환자모집
2024년 10월: CSR 결과보고서및 식약처 허가심사추가 진행

3 2023년 7월-8월 3개병원 IRB 임상시험 심사접수하여
IRB 보완요청 대응

2 2023년 3월: 3개 임상병원 확정
4월: 임상 프로토콜 작성 완료 및 식약처에 임상계획 승인 신청,
5월-6월: 식약처 임상 보완요청 대응

1 2023년 2월 임상프로젝트 개시

www.kbiotechsolutions.com

상기 타임라인은 식약처 승인시점및 환자모집속도에 따라 변동될 수 있습니다.

KBIO Solutions 임상시험 진행 CRO 견적서

No.	전향적 다기관 130명 모집 무작위배정 임상시험
1	**RCT 비교 임상시험 프로토콜 작성, 설계 및 3개 임상병원 섭외, 확정**
2	식품의약품안전처 IDE 접수 파일 준비, 식약처 임상시험 승인 신청, 식약처 임상 보완 대응 및 임상계획 승인 취득
3	**책임연구자 임상병원 교수와 작업 1 IRB 심사접수파일 준비, IRB 심사접수 신청, IRB 심사 보완대응 및 승인 취득**
4	임상병원 2 IRB 심사접수파일 준비, IRB 심사접수 신청, IRB 심사 보완대응 및 승인 취득
5	**임상병원 3 IRB 심사접수파일 준비, IRB 심사접수 신청, IRB 심사 보완대응 및 승인 취득**
6	임상시험 프로젝트 개시 위한 3개병원 임상 파일 준비, 3개병원 임상시험 개시
7	**임상병원 1 임상시험 모니터링 시행: 1년 기간**
8	임상병원 1임상시험 데이타관리, 증례기록서 작업: 1년 기간
9	**임상병원 1 임상시험 TMF 임상파일관리: 1년 기간**
10	임상병원 1 STOPSEAL PLUS 임상시험 파일 IRB 보고수행, 식약처 보고 수행
11	**임상병원 2 임상시험 모니터링 시행: 1년 기간**
12	임상병원 2 STOPSEAL PLUS 임상시험 데이타관리, 증례기록서 작업 1년 기간
13	**임상병원 2 STOPSEAL PLUS 임상시험 TMF 임상파일관리: 1년 기간**
14	임상병원 2 STOPSEAL PLUS 임상시험 IRB 보고수행, 식약처 보고 수행
15	**임상병원 3 임상시험 모니터링 시행: 1년 기간**
16	임상병원 3 임상시험 데이타관리, 증례기록서 작업: 1년 기간
17	**임상병원 3 TMF 임상파일관리: 1년 기간**
18	임상병원 3 임상시험 IRB 보고수행, 식약처 보고 수행
19	**3개 임상병원 130명 임상 Close-out: 종료작업**
20	3개 임상병원 130명 임상 데이타 통계분석
21	**3개 임상병원 결과보고서 작성**
	Total

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FDA 2등급 인허가 컨설팅

FDA 510(k)승인 취득을 위해
FDA 의료기기 2등급 인허가 타임라인을 감안한 맞춤형
FDA 510(k) 인증계획 전략을 설계

- Non-Clinical Performance Testing consulting
- Software 문서 작성 (SRS, SDS, FMEA, Verification and Validation Documentation 등)
- Complete substantial equivalence comparison consulting
- Labeling/manual

9개월 걸쳐 안전성,
비임상 성능시험 진행 컨설팅 제공

FDA 행정심사:
FDA issues RTA or Later issues
Deficiency Letter with AI request

RTA 심사 이후 실질 심사 보완으로 180일의 보완 대응기간 부여:
FDA 보완요청사항 대응진행

3개월 | 6개월 | 9개월 | 12개월 | 15개월 | 16-20개월

FDA 인증
컨설팅 계약체결

Software 문서, 비임상 성능시험 성적서들과
더불어 FDA 인허가 접수파일을 완성하여
FDA에 접수

FDA의 실질 심사 보완사항
발급: Deficiency Letter 수취

FDA 보완사항 대응:
추가 비임상 시험 진행

FDA 행정심사를 마치고 FDA 심사 90일을 포함한
FDA 보완 대응 진행

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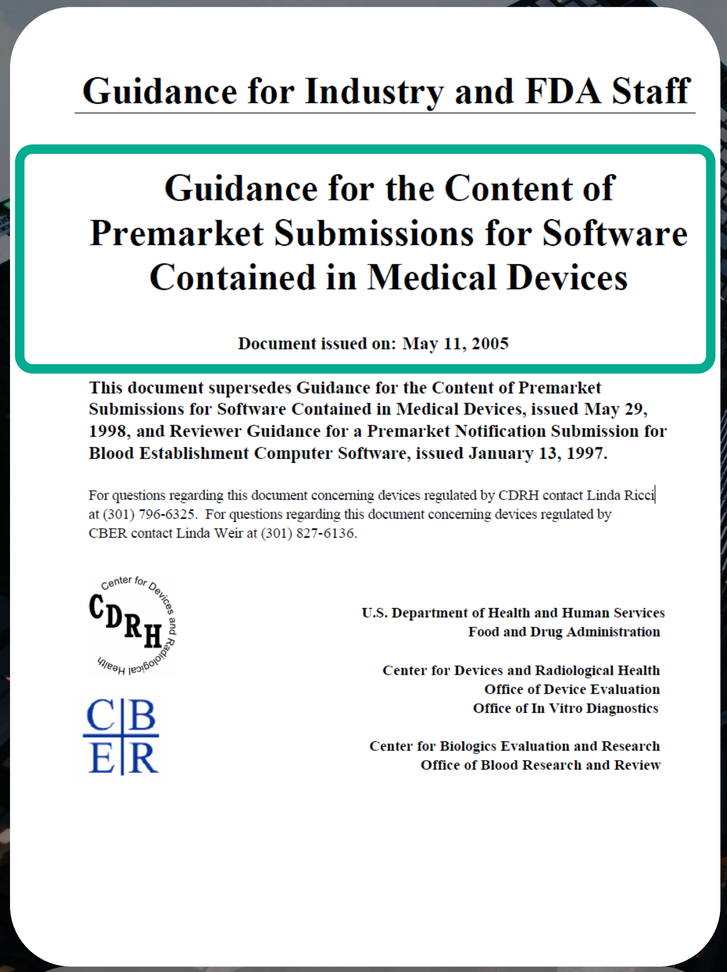
KBIO FDA 510(k) 인허가 전략



Guidance for Industry and FDA Staff

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Document issued on: May 11, 2005

This document supersedes Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 29, 1998, and Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software, issued January 13, 1997.

For questions regarding this document concerning devices regulated by CDRH contact Linda Ricci at (301) 796-6325. For questions regarding this document concerning devices regulated by CBER contact Linda Weir at (301) 827-6136.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Office of Device Evaluation
Office of In Vitro Diagnostics

Center for Biologics Evaluation and Research
Office of Blood Research and Review

FDA 가이던스에 따라
Software 문서(SRS, SDS, FMEA,
Verification and Validation
Documentation 등)를 준비할 겁니다.

출처: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices

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KBIO FDA 510(k) 인허가 전략

Table 3. Documentation Based on Level of Concern

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
Level of Concern	A statement indicating the Level of Concern and a description of the rationale for that level.		
Software Description	A summary overview of the features and software operating environment.		
Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigations.		
Software Requirements Specification (SRS)	Summary of functional requirements from SRS.	The complete SRS document.	
Architecture Design Chart	No documentation is necessary in the submission.	Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.	
Software Design Specification (SDS)	No documentation is necessary in the submission.	Software design specification document.	
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing.		
Software Development Environment Description	No documentation is necessary in the submission.	Summary of software life cycle development plan, including a summary of the configuration management and	Summary of software life cycle development plan. Annotated list of control documents generated during development process. Include the

FDA 가이던스에 따라
Software 문서(SRS, SDS, FMEA, Verification and Validation Documentation 등)를 준비할 겁니다.

출처: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices

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미국 FDA 510 (k) 인증 컨설팅

Traditional Premarket Notification 프로세스

FDA 510(k) 승인취득 위한

A 기허가 제품과의 동등비교 내용작성

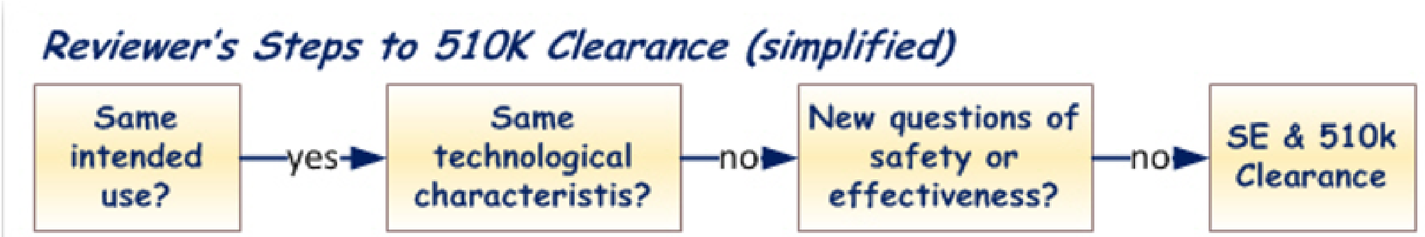
KBIO Solutions

미국 FDA 510 (k) 인증취득을 위한 컨설팅 제공
Traditional Premarket Notification 프로세스 준비

A

- FDA 510(k) 준비에 있어서 중요한 부분은 사용목적이 동일한 또는 동등하다고 판단되는 기허가 제품 (이미 510k 취득되어 시판되고 있는 제품) 을 선정하는 것입니다.

- 해당 의료기기가 사용목적은 동일하나 제품의 기술적 측면이 향상된 부분이 있을 경우에는 그 상이한 기술적 측면이 안전성과 유효성에 있어 새로운 문제를 제기하지 않는 이상 510(k) clearance 를 취득할 수 있습니다.



- 위의 언급된 절차를 일반 510(k) (Traditional 510k)라고 하며 FDA는 법적으로 90일이내에 510(k) clearance 또는 반려의 결정을 내려야 합니다.

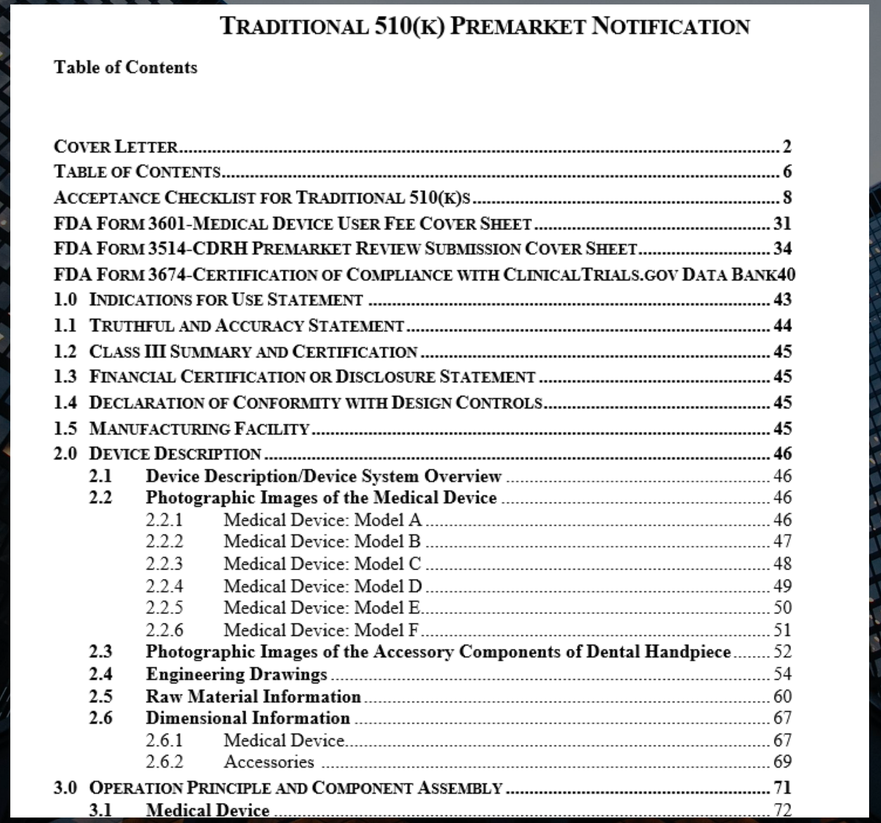
- 사용목적이 동일할 뿐만 아니라 기술상 측면도 기허가 제품과 동일 또는 동등하다고 판단되면 Special 510(k) 절차를 밟을 수 있으며, FDA는 30일이내에 510(k) clearance 결정을 내려야 합니다.

KBIO Solutions

미국 FDA 510 (k) 인증취득을 위한 컨설팅 제공

Traditional Premarket Notification 프로세스 준비

A



TRADITIONAL 510(K) PREMARKET NOTIFICATION

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