Cortellis Regulatory Intelligence

Medical Devices and IVDs Intelligence Report

FDAにて510Kクリアランス済みのPredicate Device一覧について、用途別に整理し個別の承認文書にアクセスする

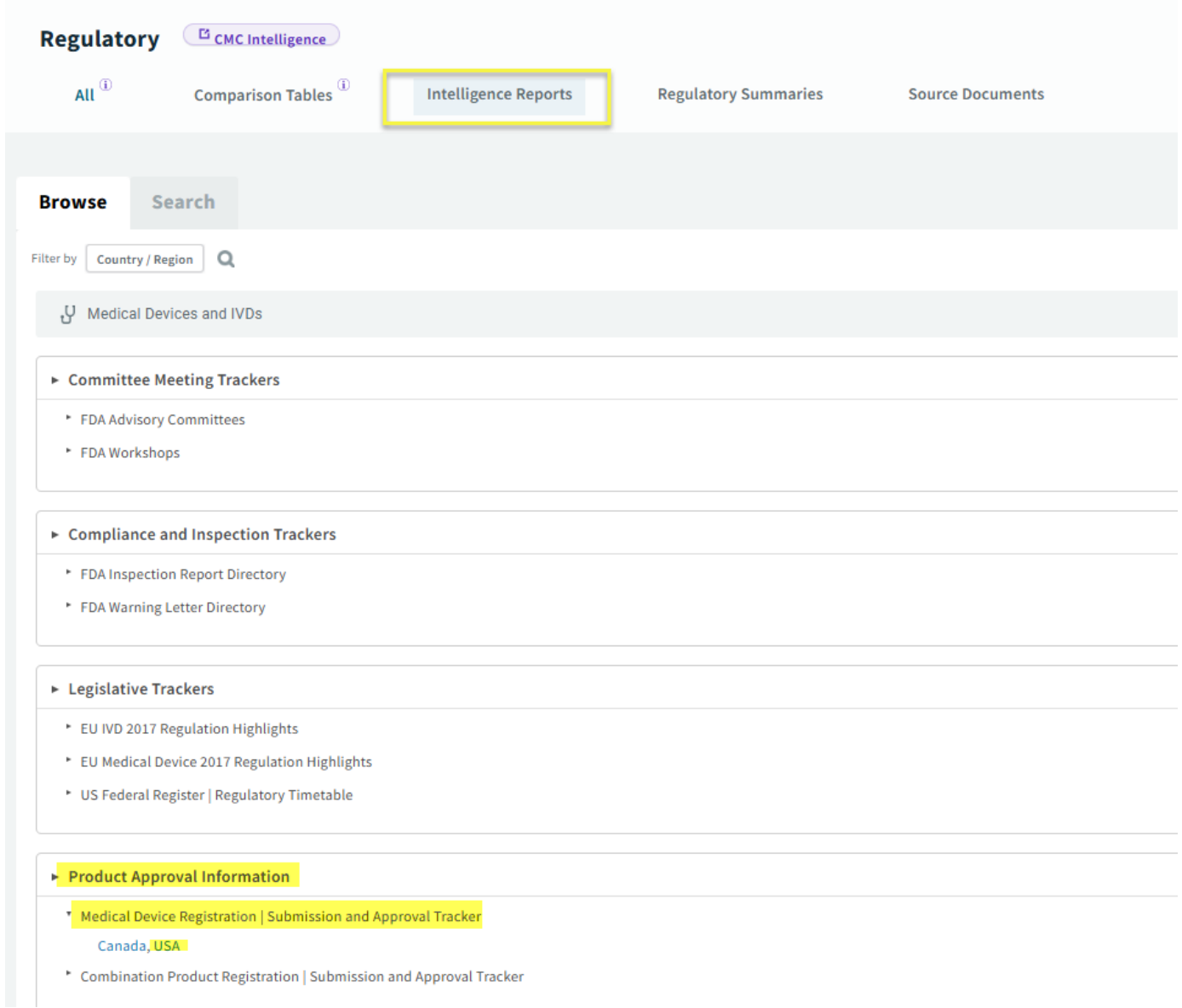
※本資料は2026年2月時点の製品の仕様に基づいて作成されております。

Intelligence Reportは速報、スプレッドシート、グラフなどの形式で提供されるCortellisの編集チームやコンサルタントが作成した付加価値レポートになります。製品の承認情報やガイドラインのモニタリング、FDAの査察対応やAdComm Meetingの準備において、お客様の作業時間の効率化に寄与します。
2026年2月時点で、以下のTOPICにて提供されています。

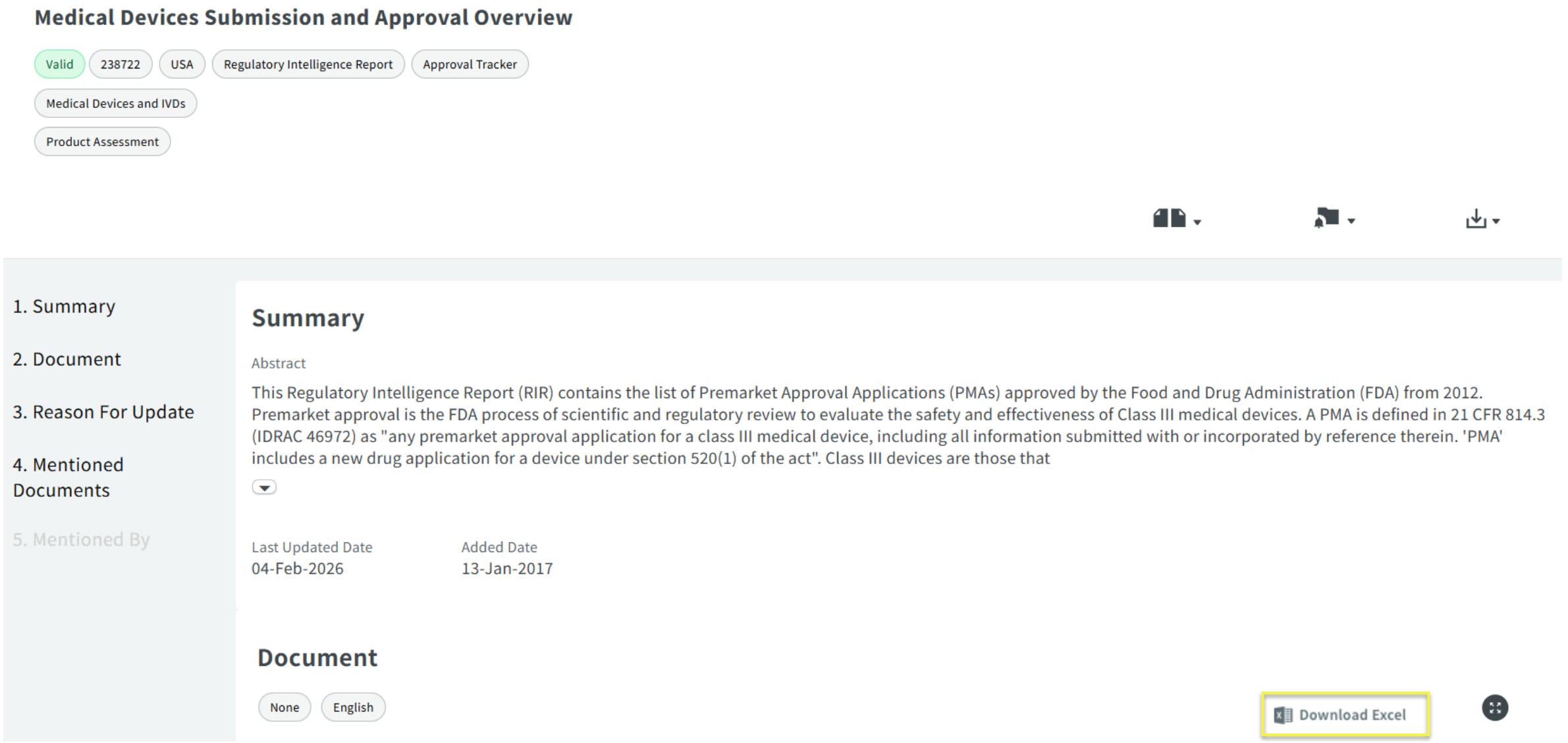
- FDA諮問委員会のAdComm会議一覧及び暫定スケジュール（新着順）
- FDA Workshop Bulletinsの一覧および暫定スケジュール（最新順）
- FDA情報公開法（FOIA）請求窓口を通じて入手したFDA査察文書
- 1997年以降に発行された医療機器関連のFDA warning letterおよびclose-out letter一覧（書簡発行日、企業名、発行センター、対象事項等含む）
- 医療機器および製薬業界関連のISO規格概要
- EU議会・理事会規則2017/746（IVDR）におけるIVD規制の主要変更点およびトピックのハイライト
- EU議会・理事会規則2017/745（MDR）における医療機器規制の主要変更点およびトピックのハイライト
- 医療機器規制に関する米国連邦官報公示のスケジュール
- 米国またはカナダにおける医療機器の申請および承認概要一覧
- FDAが1997年以降に承認した21 CFR 3.2(e)で定義されるコンビネーション製品リストおよびEUにて最初のEPAR提出以降で承認されたコンビネーション製品一覧
- オーストラリア、中国、日本、大韓民国におけるパブリックコメント募集文書とその結果一覧（草案および最終版含む）
- Cortellisに収録されている各国規制当局の発出文書に記載された用語について、現地語と英語での定義一覧

Clarivate™

US Medical Device Registration | Submission and Approval Trackerでは、米国にて2012年以降に承認された医療機器の承認文書一覧を提供しています。まずは下図の手順にて、国名をクリックします。（Product Approval Informationのカテゴリにあ るMedical Device Registration | Submission and Approval Trackerを展開します）



次に下図の黄色枠をクリックし、FDA承認済みの医療機器リストを出力します。



使用目的（Intended Uses）、カテゴリ、クラスなどから510Kクリアランス済みのデバイス一覧を、スプレッドシート内のフィルター機能を利用して整理します。

Product Name	Application Number	Product Class	Review Category	Intended Use(s)	Legal Basis	Product Code	Company	pt Date	Approval Date	Link to Product Approval Document
Unimed Reusable SpO2 Sensor: U403S-08	K251691	II	Anesthesiology ; Car	Unimed Reusable SpO Sensors are indicated for the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) in adult patients weighing greater than 30 kg who are either well or poorly perfused, when applied to the finger. The device is intended for use under no-motion conditions in professional healthcare environments. These devices are for prescription use only.	21 CFR 870.2700	DQA	Unimed Medical Supplies Inc.	02-6-2025	01-12-2025	422907
Deseyne (vifilcon C) Daily Disposable Soft (	K251683	II	Ophthalmic	Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic	21 CFR 886.5925	LPL	Bruno Vision Care LLC	30-5-2025	23-12-2025	422904
DIMPLO Implant System	K251605	II	Dental	DIMPLO Implant System is intended:- For use in the m	21 CFR 872.3640	DZE	DIMPLO Ltd.	27-5-2025	22-12-2025	422898
Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7	K251601	II	Radiology	Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus	21 CFR 892.1550	IYN	Shenzhen Mindray Bio-medical	27-5-2025	03-12-2025	422882
Intellidrop	K251598	II	Neurology	Intellidrop is indicated for use to provide external drai	21 CFR 882.5550	JXG	BrainSpace Inc.	27-5-2025	10-12-2025	422880
Erapid with Etrack System	K251572	II	Anesthesiology	Erapid with Etrack System is to be used with patients	21 CFR 868.5630	CAF	PARI Respiratory Equipment	22-5-2025	19-12-2025	422864
Overjet CBCT Assist	K251514	II	Radiology	Overjet CBCT Assist is a software for the analysis of c	21 CFR 892.2050	QIH	Overjet Inc.	16-5-2025	05-12-2025	422821
Endura Ureteral Stent and Stent Set	K251469	II	Gastroenterology/Ur	Endura Ureteral Stent and Stent Set is indicated to reli	21 CFR 876.4620	FAD	CatheGenix (Xiamen) Co. Ltd.	13-5-2025	19-12-2025	422813
Oxygen Concentrator (J10A)	K251534	II	Anesthesiology	The Oxygen Concentrator provide supplemental oxyge	21 CFR 868.5440	CAW	Foshan KYCARE Medical Equipr	19-5-2025	29-12-2025	422809
UltraSight Guidance	K251416	II	Radiology	UltraSight Guidance is:- Intended to assist medical pr	21 CFR 892.2100	QJU	UltraSight Ltd.	07-5-2025	17-12-2025	422806
LIA-1 Catheter (542-1)	K251402	II	Anesthesiology ; Ear	LIA-1 Catheter (542-1) is intended :- For use through a	21 CFR 874.4680	KTI	Leadoptik Inc.	06-5-2025	19-12-2025	422803
LED Therapy Mask (SR11CM, SR11CM1, SR	K252994	II	General & Plastic Sur	The LED Therapy Mask is indicated for use below:- Ac	21 CFR 878.4810	OHS	Guangdong Ace-Tec Co. Ltd.	18-9-2025	08-12-2025	422800
Thermo Scientific Oxoid Gepotidacin Disc (	K251337	II	Microbiology	Thermo Scientific Oxoid Antimicrobial Susceptibility Te	21 CFR 866.1620	JTN	Thermo Fisher Scientific (Oxoid	30-4-2025	05-12-2025	422771
Optimesh Multiplanar Expandable Interbod	K251302	II	Orthopedic	Optimesh Multiplanar Expandable Interbody Fusion Sy	21 CFR 888.3085	OQB	Spineology Inc.	28-4-2025	15-12-2025	422767
Diagnostic Ultrasound System (Nano C5, N	K251268	II	Radiology	Diagnostic Ultrasound System (Nano C5, Nano C5 EXP	21 CFR 892.1550	IYN	Edan Instruments Inc.	24-4-2025	23-12-2025	422765

医療機器のクラス分類

医療機器の対象カテゴリ

医療機器の使用目的

製品ごとにウェブリンクを介して承認文書にアクセス可能です。

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Diagnostic Ultrasound System (Nano CS, N	K251268	II	Radiology	Diagnostic Ultrasound System (Nano CS, Nano CS EX	21 CFR 892.1550	IYN	Edan Instruments Inc.	24-4-2025	23-12-2025	422765

510(k) Premarket Notification K251691: UNIMED REUSABLE SPO2 SENSOR: U403S-08, 01-Dec-2025

Valid | 422907 | USA | Reference Document | 510(k)

Medical Devices and IVDs

Anesthesiology | Cardiovascular

Product Assessment

1. Summary
2. Snapshot
3. Document
4. Reason For Update
5. Mentioned Documents
6. Mentioned By

Summary

Abstract

On December 01, 2025, FDA cleared 510(k) premarket notification K251691 for UNIMED REUSABLE SPO2 SENSOR: U403S-08.

Device Name: UNIMED REUSABLE SPO2 SENSOR: U403S-08

510(k) Number: K251691

Company: Unimed Medical Supplies, Inc.

Intended Use(s): They are indicated for the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) i are either well or poorly perfused, when applied to the finger. The device is intended for use under no-motion conditions in professional healthcare environments.

Regulation Number: 21 CFR 870.2700

Regulation Name: Cardiovascular Monitoring Devices, Oximeter

Product Code: DQA

Review Panel: Anesthesiology

Decision: Substantially Equivalent (SESE)

Type: Traditional

Class: II

FDA U.S. FOOD & DRUG ADMINISTRATION

December 1, 2025

Unimed Medical Supplies, Inc.
Huanyu Zeng
Regulatory Affairs Specialist
Bld#8, Nangang 3rd Industrial Park, Tangtou,
Shiyan, Baoan District
Shenzhen, 518108
China

Re: K251691
Trade/Device Name: Unimed Reusable SpO2 Sensor: U403S-08
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: October 30, 2025
Received: October 30, 2025

Dear Huanyu Zeng:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration

About Clarivate

Clarivate is a leading global provider of transformative intelligence. We offer enriched data, insights & analytics, workflow solutions and expert services in the areas of Academia & Government, Intellectual Property and Life Sciences & Healthcare. For more information, please visit clarivate.com.