



Cortellis Regulatory Intelligence

Medical Devices and IVDs Intelligence Report

米国情報公開法 (FOIA) を介して入手したFDAの査察情報一覧を確認する

※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。

© 2026 Clarivate. All rights reserved.

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

ここでは、米国の情報公開法 (FOIA) を利用して入手したFDAの査察レコード一覧 (EIR, Form 483およびCorrespondenceをリストアップ) を提供するIntelligence Reportへのアクセス方法を紹介します。まず下図の手順にて、Compliance and Inspection TrackersからFDA Inspection Report Directoryを展開し、国名 (米国) をクリックします。

The screenshot shows a web interface for regulatory intelligence reports. At the top, there is a 'Regulatory' section with five tabs: 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The 'Intelligence Reports' tab is highlighted with a yellow box. Below this, there are 'Browse' and 'Search' buttons. A 'Filter by' dropdown menu is set to 'Country / Region'. Underneath, there is a 'Medical Devices and IVDs' section. The 'Committee Meeting Trackers' section is expanded, showing 'FDA Advisory Committees' and 'FDA Workshops'. The 'Compliance and Inspection Trackers' section is also expanded, showing 'FDA Inspection Report Directory' and 'FDA Warning Letter Directory'. Under 'FDA Inspection Report Directory', the 'USA' filter is highlighted with a yellow box.

次に下図の黄色枠をクリックすることで、以下の情報がまとめられた査察情報の一覧表をダウンロード可能です。

FDA Inspectors Table: Inventory of EIR, FDA 483 and Correspondence

Valid 71070 USA Regulatory Intelligence Report Inspection Report
Drugs and Biologics Medical Devices and IVDs
No specific Specialty
Compliance and Inspection

- 査察開始日・終了日、FDA査察官の名前
- FDA District Office、FDAセンター
- 査察を受けた会社または個人（臨床研究者）
- 査察の州/国
- 査察を受けた施設タイプ
- プロジェクトエリアの情報
- 査察分類（NAI: No Action Indicated, VAI: Voluntary Action Indicated, OAI: Official Action Indicated）
- 査察タイプ
- 関連するdocumentへのリンク（EIR, FDA483, Correspondence, Warning Letter）



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

Summary

Abstract

This Regulatory Intelligence Report (RIR) contains all FDA inspection documents obtained by Cortellis through FDA FOIA request office. FDA inspection documents include the following reports:

- Establishment Inspection Report (EIR): detailed record of an inspection written by FDA inspectors after each inspection conducted.
- FDA Form 483: when an investigator has observed any violations of the Food, Drug, and Cosmetic (FD&C) Act and related Acts, a Form 483 is sent to the company. This is a summary of the deficiencies found during the inspection to bring the company into compliance. Sometimes, if no



Last Updated Date
04-Feb-2026

Added Date
30-Jul-2007

Document

None English

Download Excel



国や地域、プロジェクトエリア等から査察情報をフィルタリングして整理することが可能です（下図では国を米国以外に指定し、プロジェクトエリアを医療機器でフィルタリングしています）。

Link to Inspection Report	Inspection Starting Date	Inspection Ending Date	FDA Inspector	FDA District Office	Center	Company or Individual Inspected	Country/Region	Type of Establishment Inspected	Project Area	District Decision	Inspection Type	Available Record	Related Letters
381896	06-9-2022	09-9-2022	Beltran, Esteban	Foreign Inspection	CDRH	Olympus Medical Systems Corporation	Japan	Specification developer	Postmarket assurance: devices	Official action indicated	Not available	483	358208 (Warning letter)
380155	15-8-2022	18-8-2022	Smith, Stephen C.	Foreign Inspection	CDRH	Centro de Construccion de Cardioestimuladores del Uruguay SA	South Africa	Manufacturer	Compliance: devices	Voluntary action indicated	Not available	483	
373425	18-7-2022	21-7-2022	Marrero, Felix J.	Foreign Inspection	CDRH	Getsch+Hiller Medizintechnik GmbH	Germany	Device manufacturer	Compliance: devices	Official action indicated	Not available	483	359804 (Warning letter)
381902	30-5-2022	02-6-2022	Laufmann, Catherine J.	Foreign Inspection	CDRH	Oticon Medical	France	Manufacturer	Compliance: devices	Not available	Not available	483	
382925	16-5-2022	19-5-2022	Creighton, Sean T.	Foreign Inspection	CDRH	Abbott Point of Care Canada Ltd.	Canada	Manufacturer	Compliance: devices	Official action indicated	Not available	483	363296 (Warning letter)
379521	15-9-2021	26-9-2021	Marrero, Felix J.	Foreign Inspection	CDRH	Unimicro Medical Systems-Shenzhen	China	Device manufacturer	Compliance: devices	Voluntary action indicated	Not available	483	344529 (Warning letter)
350516	27-1-2020	30-1-2020	Goodrich, Rosanna	Foreign Inspection	CDRH	Laboratorios Dentales De Zona Franca	Costa Rica	Device manufacturer	Compliance: devices	Official action indicated	Not available	483	336214 (Warning letter)
343490	20-1-2020	23-1-2020	Sciacchitano, John A.	Foreign Inspection	CDRH	Sooil Development Co Ltd.	South Korea	Manufacturer	Compliance: devices	Voluntary action indicated	Not available	483	
343487	13-1-2020	16-1-2020	Sciacchitano, John A.	Foreign Inspection	CDRH	PIXXGEN Corporation	South Korea	Device manufacturer	Postmarket assurance: devices	Voluntary action indicated	Not available	483	
350500	07-1-2020	10-1-2020	Duong, Thai T.	Foreign Inspection	CDRH	Bk Meditech Co. Ltd.	South Korea	Device manufacturer	Compliance: devices	Official action indicated	Not available	483	
346254	06-1-2020	09-1-2020	Montero, James R.	Foreign Inspection	CDRH	Co-Innovation Biotech Co. Ltd.	China	Device manufacturer	Postmarket assurance: devices	Voluntary action indicated	Not available	483	
382929	28-10-2019	31-10-2019	Rodriguez, Karen M.	Foreign Inspection	CDRH	Bedfont Scientific	United Kingdom	Manufacturer	Compliance: devices	Official action indicated	Not available	483	
307622	27-10-2019	30-10-2019	Laufmann, Catherine J.	Foreign Inspection	CDRH	Jieying Laboratory	Canada	Manufacturer	Compliance: devices	Not available	Not available	483	
319997	07-10-2019	10-10-2019	Pulver, Janet	Foreign Inspection	CDRH	Global Medical Technology SL	Spain	Device manufacturer	Compliance: devices	Official action indicated	Not available	483	
356109	13-6-2019	21-6-2019	Khan, Farhana	Foreign Inspection	CDRH	Dr. Reddy's Laboratories Ltd.	India	Manufacturer	Compliance: devices	Voluntary action indicated	Not available	483	
356109	13-6-2019	21-6-2019	Burgos Garcia, Monica C.	Foreign Inspection	CDRH	Dr. Reddy's Laboratories Ltd.	India	Manufacturer	Compliance: devices	Voluntary action indicated	Not available	483	
356136	03-6-2019	11-6-2019	Khan, Farhana	Foreign Inspection	CDRH	Sun Pharmaceutical Industries Ltd.	India	Manufacturer	Compliance: devices	Voluntary action indicated	Not available	483	
356136	03-6-2019	11-6-2019	Burgos Garcia, Monica C.	Foreign Inspection	CDRH	Sun Pharmaceutical Industries Ltd.	India	Manufacturer	Compliance: devices	Voluntary action indicated	Not available	483	
319213	27-5-2019	30-5-2019	Duong, Thai T.	Foreign Inspection	CDRH	ITL Asia Pacific Sdn Bhd	Malaysia	Device manufacturer	Compliance: devices	Official action indicated	Not available	483	306962 (Warning letter)
381890	07-8-2018	29-8-2018	Mutawakil, Ashley	Foreign Inspection	CDRH	Merate Medical GmbH	Germany	Specification developer	Compliance: devices	Voluntary action indicated	Not available	483	351723 (Warning letter)

査察の開始日および終了日

査察実施国

査察対象フィールド
(医療機器、医薬品
など)

エクセルファイル内のウェブリンクから個別の査察レポートやWarning Letterへアクセスすることが可能です。

Summary

Abstract

Inspection of: Olympus Medical Systems Corporation (Tokyo, Japan)

Region: Foreign Inspection

Type of Establishment: Specification Developer

Inspector: Esteban Beltran

District Decision: OAI

Observation: MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

N.B.: This document has been prepared by integrating FDA documents acquired under the Freedom of Information Act, into one comprehensive document.



Last Updated Date	Added Date	Authority Acceptance Date	Source Publication Date
10-Sep-2024	04-Apr-2024	09-Sep-2022	04-Apr-2024

Document

English

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 Fax: (301) 594-4715	DATE(S) OF INSPECTION 9/6/2022-9/9/2022 FACILITY NUMBER 3002807795
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Tomohisa Sakurai, President	
FIRM NAME Olympus Medical Systems Corporation	STREET ADDRESS 2951 Ishikawa-machi
CITY, STATE, ZIP CODE, COUNTRY Hachioji-shi, Tokyo, 192-8507 Japan	TYPE ESTABLISHMENT INSPECTED Specification Developer
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.	
<i>The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system</i>	

Summary

Abstract

An inspection of Olympus Medical Systems Corporation (Tokyo, Japan) revealed that firm's manufactures gastrointestinal and surgical endoscopes were misbranded under section 502 of the Act in that firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act and 21 CFR Parts 803. The following deviations was observed: Failed to submit a report to FDA no later than 30 calendar days.

One deviation is reviewed in this warning



Last Updated Date	Added Date	Authority Acceptance Date	Source Publication Date
08-Mar-2024	12-Jan-2023	12-Dec-2022	12-Jan-2023

Document

English

WARNING LETTER
Olympus Medical Systems Corporation
MARCS-CMS 649726 -- DECEMBER 12, 2022

Product:
Medical Devices

Recipient:
Tomohisa Sakurai
President
Olympus Medical Systems Corporation
2951, Ishikawa-cho
Hachioji-shi, Tokyo 192-8507
Japan

Issuing Office:
Center for Devices and Radiological Health



Think forward

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.

© 2026 Clarivate. All rights reserved

Clarivate and its logo, as well as all other trademarks used herein are trademarks of their respective owners and used under license.