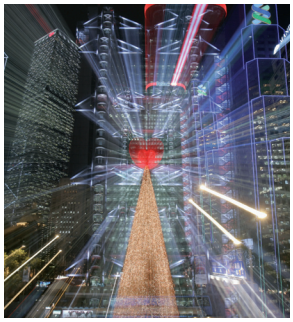
CORTELLIS REGULATORY INTELLIGENCE MEDICAL DEVICE COVERAGE

THE SINGLE SOURCE OF TRUSTED REGULATORY INTELLIGENCE FROM THOMSON REUTERS



HOW IS CORTELLIS REGULATORY INTELLIGENCE DIFFERENT?

- Unmatched depth of regulatory intelligence
- Unparalleled regulatory expertise
- Alerts on regulatory changes as they happen
- Combined searches across multiple countries

WHY USE CORTELLIS REGULATORY INTELLIGENCE?

- Increase compliance
- File in multiple countries
- Save time and cost
- Optimize your regulatory strategy

Cortellis™ Regulatory Intelligence from Thomson Reuters is a comprehensive regulatory intelligence solution. It provides professionals involved in the clinical development, launch and post-marketing surveillance of drugs, with reliable and accurate global regulatory information to gain competitive advantage, and minimize regulatory risks.

As a comprehensive regulatory solution, Cortellis Regulatory Intelligence helps you make timely and more informed decisions for your medical devices by providing you with exclusive regulatory information for multi-country filing, comparing existing and emerging competitive products, preparing for committee meetings and inspections, and keeping up-to-date on regulatory changes as they happen.

EU MODULE

REFERENCE DOCUMENTS:

- The Medical Device Directive
- The Active Implantable Medical Devices Directive
- The In Vitro Diagnostics Directive
- MEDDEV guidelines

The module also contains information on other directives such as the EU Waste Electrical and Electronic Equipment Directive 2002/96/EC, Directive 2005/50/EC on Reclassification of Hip, Knee and Shoulder Joint Replacements, and Directive 2003/32/EC for Devices Manufactured Utilizing Tissues of Animal Origin.

REGULATORY SUMMARIES:

- How to market medical devices
  - Definition
  - Legal framework including European directives, classification, essential requirements, competent authorities, notified bodies and authorized representative
  - Requirements for design and compliance including standards, technical dossier, risk management and preclinical assessment
  - Clinical evaluation
  - Labeling requirements, including CE marking
  - Post-marketing requirements
  - Fees
  - Pricing and reimbursement
  - Advertising
  - International aspects (GHTF, GMDN, MRAs , PECAS)
  - Overview of human tissue engineered products
  - REACH, GHS
  - Checklists
- How to market drug/drug combination products
- How to market advanced therapy products
- Regulatory summaries include links to all relevant reference documents

U.S. MODULE

REFERENCE DOCUMENTS:

- Major acts within the scope of Cortellis Regulatory Intelligence, including Medical Device User Fee and Modernization Act and the U.S. Food and Drug Administration (FDA) Amendments Act of 2007
- Code of Federal Regulations (CFR) 21 CFR Parts 800 to 898 (2005–present) — CFR is updated in blue text as final rules become effective and the amended text remains in blue for one year
- Federal Register — all proposed and final rules affecting the CFR, including the Center for Devices and Radiological Health (CDRH) guidances
- CDRH guidances (2005–present) related to therapeutic use
- FDA Enforcement Reports

REGULATORY SUMMARIES:

- How to market medical devices
  - Definition
  - Legal framework
  - Requirements for registration format and content of applications
  - Clinical research
  - Fees
  - Labeling requirements
  - Post-marketing requirements
  - Pricing and reimbursement
  - Advertising
  - Federal pre-emption
  - International aspects

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AVAILABLE MODULES

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- Russia
- The Netherlands
- Tunisia
- South Korea
- UK
- U.S.

- How to market combination products
- How to market advanced therapy products
- Regulatory summaries include links to all relevant reference documents

CANADA MODULE

REFERENCE DOCUMENTS:

- Medical Devices Regulations
- Comprehensive list of guidelines and application forms (provided in ready-to-use format)
- Safety information
- Policy type documents
- More than 10 years of meeting records from Canada's Medical Device Technology Companies and Health Canada
- Notices of Decision
- Summary Basis of Decision
- Operator's manual
- Package insert

REGULATORY SUMMARIES:

- How to market medical devices
  - Definition
  - Legal framework
  - Requirements for registration/format and content of applications
  - Fees
  - Clinical research
  - Labeling
  - Post-marketing requirements
  - Pricing and reimbursement
  - Advertising
  - Includes links to all relevant reference documents

REGULATORY INTELLIGENCE REPORT:

A comprehensive medical devices approval information Excel file detailing product name and class, applicant, application and license number, type of approval (standard/conditional), and intended use.

With links to the authorities approval information (Notices of Decision, Summary Basis of Decision) and applicants instructions (operator's manual, package insert)

Check out:

Medical Device Daily — the Daily Medical Technology News Source for insightful and up-to-the-minute news coverage on innovative new product development, strategic deals shaping the future of med-tech, locating capital sources, updates of new regulatory actions by the FDA and other agencies, plus more. For more information, click here:

http://thomsonreuters.com/products/ip-science/medical-device-daily/medical-device-daily.pdf

REGULATORY INTELLIGENCE REPORTS

The regulatory specialists with Cortellis Regulatory Intelligence have developed exclusive reports to support the daily laborious task of monitoring and analyzing regulatory data, so you can spend your time making strategic decisions. Use the comparative tables within Cortellis Regulatory Intelligence for multi-country filing in Europe, stay ahead of EU and U.S. legislations and guidelines with amended versions and histories to prepare and adjust your strategic plans. Also compare existing or emerging competitive products using the product approval information, or identify potential new indications for your products using the Cortellis Regulatory Intelligence's summary table of Waivers and Paediatric Investigation Plan. You can also prepare for committee meetings and inspections with the Cortellis Regulatory Intelligence committee summaries, member profiles, voting histories, and FDA inspector tables.

REGULATORY SUMMARIES

Use the regulatory summaries within Cortellis Regulatory Intelligence to support your country filings and guide you through each country's registration process. These summaries are entirely in English, are continuously updated by our regulatory experts and local consultants, and cover the product lifecycle from development through to post-marketing. Or simply utilize the "How to Market" information to help you decide the most efficient submission routes for your products.

REFERENCE DOCUMENTS

Cortellis Regulatory Intelligence provides you with a complete collection of published regulatory documents available from more than 200 sources. This repository is home to more than 100,000 documents which dates back to 1885 and is updated daily with the latest regulatory developments across the globe. The tracking of versions for documents is available through tables and hyperlinks to help you get to the information you need fast. Exclusive English translations are also available for documents in the Cortellis Regulatory Intelligence China, Japan, South Korea, and Taiwan modules.

WITH CORTELLIS REGULATORY INTELLIGENCE YOU CAN:

- **Save time -** Spend more time making decisions, and not searching for information.
- **Act quickly -** Get regulatory changes as they happen.
- **Act decisively -** Make more informed decisions with the most comprehensive source of regulatory information available.
- **Be prepared -** Get inside information on advisory committee decisions, submission mistakes to avoid, FDA inspections, and more.

CE marking	=	European conformity marking
GHTF	=	Global Harmonization Task Force
GMDN	=	Global Medical Devices Nomenclature
MRAs	=	Mutual Recognition Agreements
PECAS	=	Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products
REACH	=	Registration, Evaluation, Authorisation and Restriction of Chemicals
GHS	=	The Globally Harmonized System of Classification and labeling of Chemicals
EIR	=	Establishment Inspection Report
FDA	=	Food and Drug Administration

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