Medical Device Databases

Title	Description	Updated	More Information
Advisory Committee/Panel Meetings - CDRH [1]	This database contains historical information about CDRH Advisory Committees and Panel meetings through 2008, including summaries and transcripts.	No longer being updated	FDA Advisory Committees and Meeting Materials [2]
CDRH Inspections Database [3]	The CDRH Inspections Database provides information about medical device inspections that were the responsibility of CDRH from 2008 to the present.	Weekly	More CDRH Inspections Database [4]
CFR Title 21 - Food and Drugs [5]	This database contains the most recent revision from the Government Printing Office (GPO) of the Code of Federal Regulations (CFR) Title 21 - Food and Drugs.	Annually	More About 21CFR [6]
Clinical Laboratory Improvement Amendments (CLIA) [7]	This database contains the commercially marketed in vitro test systems categorized by the FDA since January 31, 2000 and tests categorized by the Centers for Disease Control and Prevention (CDC) prior to that date.	Weekly	Clinical Laboratory Improvement Amendments - Download Data [8]
FDA Certified Mammography Facilities [9]	A searchable listing by state and zip code of all mammography facilities certified by the Food and Drug Administration (FDA) as meeting baseline quality standards for equipment, personnel and practices under the Mammography Quality Standards Act of 1992 (MQSA).	Weekly	
IVD Home Use Lab Tests (Over The Counter) Tests [10]	Searchable listing of Over-the-Counter tests (OTC) and collection kits that have been cleared or approved by the FDA	Weekly	More about Home Use Lab Tests [11]
MAUDE (Manufacturer and User Facility Device Experience) [12]	MAUDE data represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June, 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August, 1996.	Weekly	
MDR (Medical Device Reporting) [13]	This database allows you to search the CDRH's database information on medical devices which may have malfunctioned or caused a death or serious injury during the years 1992 through 1996.	No longer being updated	
NHRIC (National Health Related Items Code) [14]	The National Health Related Items Code (NHRIC) is a system for identification and numbering of marketed device packages that is compatible with other numbering systems such as the National Drug Code (NDC) or Universal Product Code (UPC). Those manufacturers who desire to use the NHRIC number for unique product identification may apply to FDA for a labeler code. This database contains NHRIC data retrieved from records that date back 20 years.	Annually	More about NHRIC [15]
Premarket Approvals (PMA) [16]	Premarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of all devices classified as Class III devices. An approved Premarket Approval Application (PMA) is, in effect, a private license granted to the applicant for marketing a particular medical device. This database may be searched by a variety of fields and is updated on a monthly basis.	Weekly	File Description for the CDRH Releasable (Approved) PMAs [17]
Premarket Approval (PMA) Summary Review Memos for 180-Day Design Changes [18]	A 180-day supplement is a request for a significant change in components, materials, design, specification, software, color additive, and labeling to an approved premarket application or premarket report. As a pilot program under the CDRH Transparency Initiative, FDA has begun releasing some summary review memos for 180-day PMA supplements relating to design changes.	Weekly	More about Premarket Approval (PMA) Summary Review Memos for 180-Day Design Changes [19]

Premarket Notifications (510 (k)s) [20]	Medical device manufacturers are required to submit a premarket notification or 510(k) if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. This database of releasable 510(k)s can be searched by 510(k) number, applicant, device name or FDA product code. Summaries of safety and effectiveness information is available via the web interface for more recent records. The database is updated monthly.	Weekly	
Product Classification [21]	This database contains medical device names and associated information developed by the Center. It includes a three letter device product code and a Device Class that refers to the level of CDRH regulation of a given device.	Weekly	More about Product Code Classification Database [22]
Radiation-emitting Electronic Product Codes [23]	This database contains product names and associated information developed by the Center for all products, both medical and non-medical, which emit radiation. It includes a three letter product code, a descriptor for radiation type, applicable performance standard(s), and a definition for the code.	Weekly	
Recalls of Medical and Radiation Emitting Devices [24]	This database contains a list of classified medical device recalls since November 1, 2002	Frequently as items become available	
Registration & Listing [25]	This searchable database contains establishments (engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution) and listings of medical devices in commercial distribution by both domestic and foreign manufacturers. Note: This database is updated once a month.	Weekly	
Total Product Life Cycle (TPLC) [26]	The Total Product Life Cycle (TPLC) database integrates premarket and postmarket data about medical devices. It includes information pulled from CDRH databases including Premarket Approvals (PMA), Premarket Notifications (510[k]), Adverse Events, and Recalls. You can search the TPLC database by device name or procode to receive a full report about a particular product line.	Weekly	More about TPLC [27]
FDA Recognized Consensus Standards [28]	This database consists of those national and international standards recognized by FDA which manufacturers can declare conformity to and is part of the information the Center can use to make an appropriate decision regarding the clearance or approval of a submission. Information submitted on conformance with such standards will have a direct bearing on safety and effectiveness determinations made during the review of IDEs, HDEs, PMAs, and PDPs. Conformance with recognized consensus standards in and of itself, however, may not always be a sufficient basis for regulatory decisions.	Quarterly	
X-Ray Assembler Data [29]	Federal regulations require that an assembler who installs one or more certified components of a diagnostic x-ray system submit a report of assembly. This database contains the releasable information submitted including Equipment Location, General Information and Component Information. Note: Data does not include dental system installations.	Annually	X-Ray Assembler Data File [30]

Links on this page:

1. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/search.cfm
2. /AdvisoryCommittees/CommitteesMeetingMaterials/default.htm
3. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
4. /AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm223770.htm
5. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
6. /MedicalDevices/DeviceRegulationandGuidance/Databases/ucm135680.htm
7. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm

8. /MedicalDevices/DeviceRegulationandGuidance/Databases/ucm142437.htm
9. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMQSA/mqsa.cfm
10. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm
11. /MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/HomeUseTests/default.htm
12. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
13. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/search.CFM
14. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfNHRIC/nhric.cfm
15. /MedicalDevices/DeviceRegulationandGuidance/Databases/ucm161456.htm
16. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
17. /MedicalDevices/DeviceRegulationandGuidance/Databases/ucm135279.htm
18. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pmamemos.cfm
19. /AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm206289.htm
20. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
21. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm
22. /MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051637.htm
23. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_rh/TextSearch.cfm
24. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm
25. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/registration.cfm
26. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
27. /AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm199906.htm
28. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
29. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAssem/assembler.cfm
30. /MedicalDevices/DeviceRegulationandGuidance/Databases/ucm135419.htm

Establishment Registration & Device Listing

This database includes:

- medical device manufacturers registered with FDA and
- medical devices listed with FDA

Note: Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by FDA.

Learn More...

Search Database Help Download Files

Establishment Name	Registration Number
Owner/Operator Name	Owner/Operator Number
Proprietary Name	Classification Device Name
Product Code	Establishment Type
Establishment State (U.S.)	Establishment Country

Quick Search Clear Form Search

Need to update your information?

To modify, add, or delete information, log onto your FURLS account.

Note: Changes will appear when the database is updated (usually every Monday).

Other Databases

- 510(k)s
- Registration & Listing
- Adverse Events (MAUDE)
- Recalls
- Premarket Approvals (PMAs)
- Inspections
- Device Classification
- Standards
- Total Product Life Cycle
- CFR Title 21

Premarket Approval (PMA)

Search Premarket Approval (PMA)

Help | Download Files | More about PMA

Applicant Name
Trade Name
Decision Date to
Notice Date to
Docket Number
Expedited Review
Product Code
PMA Number P

Advisory Committee
Cleared/Approved IVD Products
Combination Products
Supplement Type
Sort by Decision Date (Descending)

For full-text search, select *Go to Simple Search* button

Go to Simple Search 10 **Records per Report Page** Search Clear

510(k) Premarket Notification

Search 510(k) Database

Download Files | More About 510(k)

510K Number K
Type
Model
Cleared/Approved IVD Products
Applicant Name
Expedited Review
Device Name
Third Party Reviewed
Panel
Product Code
Decision
Decision Date to
Clinical Trials
Sort by Decision Date (descending)
Combination Products

Go to Simple Search Clear 10 **Records per Report Page** Search

資料 7

Quick Links: Skip to main page contentSkip to SearchSkip to Topics MenuSkip to Common Links

Devices@FDA

Devices@FDA about Devices@FDA | help

Enter a search term in the space below.

Optional:

Approval Date From:

To: 02/16/2012

search clear 10 Records per Report Page

sort by: Approval Date Device Name

Devices@FDA is a catalog of cleared and approved medical device information from fda. it includes links to the device summary information, manufacturer, approval date, user instructions, and other consumer information. Devices@FDA searches the following databases:

PMN-510(k) Premarket Notification PMA-Premarket Approval

We welcome your comments and feedback about Devices@FDA.

資料8

European Commission

European Commission Consumers Policy Professionals ... Market surveillance and vigilance EUDAMED

European Databank on Medical Devices - EUDAMED

The Medical Device Directives contain provisions on a European databank for medical devices, which has been developed under the name Eudamed. The aim of Eudamed is to strengthen market surveillance and transparency in the field of medical devices by providing Member State competent authorities with fast access to information on manufacturers and authorized representatives, on devices and certificates and on vigilance and clinical investigation data, as well as to contribute to a uniform application of the Directives, in particular in relation to registration requirements.

Which information is stored in Eudamed?

Depending on the applicable directive, Eudamed contains data on:

- **registration of manufacturers, authorized representatives and devices**,
- data relating to **certificates issued, modified, supplemented, suspended, withdrawn or refused**,
- data obtained in accordance with the **vigilance procedure** and
- data on **clinical investigations**.

Who can access Eudamed?

Eudamed is a secure web-based portal acting as a central repository for information exchange between national competent authorities and the Commission and **is not publicly accessible**. Eudamed use is obligatory since May 2011.

Impact of Eudamed on IVD notifications

With the implementation of Eudamed, the **transitional provision** in Article 10 of Directive 98/79/EC, which obliges IVD manufacturers to give notification to every Member State concerned by the placing on the market of devices, **cease to apply**.

GMDN use in Eudamed

An important tool for Eudamed is the **Global Medical Device Nomenclature (GMDN)**. The development of GMDN started with a mandate to CEN for the development of a structure for a medical device nomenclature. The result, the European standard EN ISO 15225 "Nomenclature - specification for a nomenclature system for medical devices for the purpose of regulatory data exchange", was further developed into a CEN technical report. Maintenance of this work was taken over by the GMDN Maintenance Agency which developed the Nomenclature (referred to as GMDN) into what it is **today, a comprehensive, regularly updated web-based nomenclature accessible to manufacturers against license fees**. GMDN presents the best practice for Eudamed purposes, even though, for the time being, data entry is also possible without providing a GMDN code.

資料9

医療機器及び医療用医薬品のFD申請率について

	医療機器（審査中のものを含む）						医療用医薬品（審査中のものを含む）					
	新規			一変			新規			一変		
	FD	書面	FD率	FD	書面	FD率	FD	書面	FD率	FD	書面	FD率
2009年度	534	273	66.2	421	93	81.9	1243	0	100	1572	0	100
2010年度	516	148	77.7	529	55	90.6	1367	0	100	2135	0	100
2011年度（4/1～12/31）	363	111	76.6	471	35	93.1	696	0	100	1507	0	100

データソース：新申請審査システムを用いた検索集計
調査： PMDA規格基準部（2012年2月6日現在）

研究成果の刊行に関する一覧表

書籍

著者氏名	論文タイトル名	書籍全体の編集者名	書　籍　名	出版社名	出版地	出版年	ページ
なし							

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
なし					