The Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
5630 Fishers Lane, Room 1061, HFZ-305
Rockville, Maryland 20852
Telephone (301) 827-6860
Fax (301) 827-6870

受領された申立書は、上記分室において、月曜から金曜の午前9時から午後4時までの間、閲覧することができる。

本法第515条(d)(4)は、PMA申請を承認するCDRHの決定に関し、すべての関係者に対して本法第515条(g)に基づく不服審査申立てを行うことを認めている。申立人は、FDAの管理業務・手続規則に関する21 CFR part 12に基づく正式審理を求めるか、または申請およびCDRHの決定について専門家の独立諮問委員会による再審査を求めることができる。申立書は、21 CFR 10.33(b)に基づく再検討申立ての書式とする。申立人は、要請する審査の形式（審理または独立諮問委員会）を指定するとともに、申立ての裏付けとなるデータおよび情報を提出し、不服審査によって解決されるべき重要な事実に関する真正かつ実質的な争点が存在することを示さなければならない。申立ての審査後、FDAは、その申立てを認めるか却下するかを決定し、その決定の通知を米国官報に公告する。FDAが申立てを認めた場合、通知には再審査の対象となる問題、再審査の形式、再審査に参加できる関係者、再審査の日時と場所、その他の詳細が明記される。

（注）21 CFR 814.19に基づき、PDPがFDAによって終了したと申告されているクラスIII機器は、PMA承認済みとみなす。

販売認可PMAデータベースの検索（資料(3)-1-5、(3)-1-6、(3)-1-7）

PMAデータベースは各種のフィールドによって検索でき、検索結果が次の形式で出力される。

- 分類名
- 一般名
- 申請者
- PMA番号
- 補足申請番号
- 商標名

・資料受領日
・承認日
・商品コード
・諮問委員会
・補足申請の種類
・補足申請の理由
・迅速承認の付与（Y/N)
・承認決定の内容

ダウンロード用 PMA／PDP ファイル
販売認可 PMA に関する情報が収められた以下の ZIP 圧縮ファイルをダウンロードすることができる。このファイルの解凍方法を示してある。通常、これらのファイルは毎月 5 日に更新される。また、ファイルの内容および各ファイルに使用されているコードの説明を示してある。医療機器の名前と関連情報が収められた商品コード分類データベースのダウンロードまたは検索も可能である。

月別 PMA リスト（標準テキスト形式)
月別のリストには、PMA、PDP、補足、および通知に関する決定についての情報が示される。これには決定日のほか、住所、装置の商標名、適応（原申請またはパネル審査の補足申請に対する承認の場合)、変更の性質などの申請情報が含まれる。また、提出回数および審査期間の要約統計もまとめられている。

市販前届出 PMN-510(k) （資料(3)-1-8)
市販前届出 PMN-510(k)は 21 CFR（連邦法規集第 21 条）に記載されている。
販売認可 510(k)に関する情報
510(k)に関する情報も PMA と同様に下記の情報が記載されている。
・一般情報
・米国官報告知
・販売認可 510(k)データベースの検索
・最終決定用の、CDRH の本質的同等物
（SE）510(k)概要または５10(k)陳述書
・510(k)ファイルのダウンロード
上記に関して、夫々の情報が検索できる。これらはＴＥＸＴまたはＰＤＦファイルにて得ることができる。
・一般情報
— 510(k)概要

— クラスⅠ除外に関して
— 新510(k)対応

・米国官報告知

・販売認可510(k)データベースの検索

パネル、510(k)番号、商品コードまたは商品名により、販売認可510(k)データベースが検索できる。検索結果は次の形式で表示される。

— 装置分類名：
— 規制番号：
— 510(k)番号：
— 装置名：
— 申請者：
— コンタクト先：
— 商品コード：
— 受付日：
— 承認日：
— 決定：
— 分類諮問委員会：
— 審査諮問委員会：
— 要約または申立：

「要約」とは、安全性および有効性情報の要約がFDAから与えられることを示す。

「申立」とは、安全性および有効性情報が510(k)申請者から入手できることを示す。

— 要約／申立／パージの区別：

「パージ」とは、情報の自由法に基づき、トレードシークレット／秘密の営利情報または個人情報を除いて510(k)申請が公開されたことを示す。

— 種別：

・従来型
・特殊
・簡略化
・廃止
・自動的なクラスIII指定に対する評価

— 第三者による審査（はい／いいえ）
— 審査促進（はい／いいえ）

最終決定用の、CDRH の本質的同等性(SE)510(k)概要、または５10(k)陳述書

CDRH Consumer Information
MDA (Medical device Approval)

このファイルからは承認された機器の総覧が見れる。この総覧は、承認日(資料(3)-1-9)、機器名（資料(3)-1-10）または機器のカテゴリ（資料(3)-1-11）にて検索ができる。
これらはテキストまたはＰＤＦファイルで構成されている。
このＤＢにおける情報は、以下の３構成からなっている。

- どのような使用目的の機器か
- どのような時に使用されるのか
- 使用してはいけない時はどのような時か

また、これらの DB は更に３または４つのファイルから構成されている。

パート１　許可の書類。　CDRH 発行の許可文書。たいていは PDF

パート２　安全性または有効性に関する概論。特別、安全性等に関する基準やガイダンスがある場合にはそれも参考にしたとの記述があり、それら基準やガイダンスまたは法律がこの WEB から引き続き見れるようにリンクされている。　テキストのものや PDF のものが混在している。これは各企業の好き好きで、どちらにせよとは決められていない。

パート３　専門的な表示　ここには、取扱説明書そのものの一部を抜き出して閲覧できるようにしてある企業が多い。使用上の注意、使用上の限度等記載されている。また、さらに企業のサイトにリンクしているものもある。これも、テキストや PDF がまちまちである。さらに必要な場合には

その他一般必要情報

一般の人が見てもわかるようなライブラリー的な要素での説明。専門的な表現ではなく、イラストを使ったもの等各種サイトとリンクしてる。教育用に、また一般個人としても医学解説書を読む感じでの説明となっている。また、団体等へリンクするようにもなっている。これら団体の推薦もあるのであろう。

以下に、この事例を一つ紹介する。その他は英文のまま参照されたい。

資料(3)-1-1

ＣＤＲＨ(Center for Devices and Radiollgical Health)のＷＥＢサイト　ヘッダー部

CDRH Databases

Title	Description	Updated
Advisory Committee/Panel Meetings – CDRH	This database contains information about upcoming CDRH Advisory Committee and Panel meetings. Historical information and links to summaries and/or transcripts are provided for recent past meetings.	Frequently as items become available
Good Guidance Practices (GGP)	The GGP database contains the current comprehensive list of all CDRH guidance documents with links to the documents. The term guidance document refers to documents prepared for CDRH staff, regulated industry and the public that relate to the processing, content, and evaluation of regulatory submissions; the design, production, manufacturing, and testing of regulated products; or to the inspection and enforcement procedures.	Frequently as items become available
CFR Title 21 – Food and Drugs	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. You can search CFR Title 21 by entering a part and section number, selecting a CFR part number from a drop down list, or by using a full text search.	Annually
Clinical Laboratory Improvement Amendments (CLIA)	This database contains the commercially marketed in vitro test systems categorized by the FDA since January 31, 2000 and test categorized by the Centers for Disease Control and Prevention (CDC) prior to that date.	Monthly
Device Listing	This database contains a listing of medical devices in commercial distribution by both domestic and foreign manufacturers.	Monthly
FDA Certified Mammography Facilities	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
MAUDE (Manufacturer and User Facility Device Experience)	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.	Quarterly
MDR (Medical Device Reporting)	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)	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
Premarket Approvals (PMA)	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.	Monthly
Premarket Notifications (510(k)s)	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	Monthly

	the web interface for more recent records. The database is updated monthly.	
Product Classification	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.	Monthly
Establishment Registration	This is a searchable database of establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution. Foreign establishments that export to the U.S are also required to register. Note: This database is updated once a month.	Monthly
FDA Recognized Consensus Standards	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
United States Agents for Devices	This database acts as an "electronic bulletin board" for any person wishing to provide service as a United States agent. The potential US Agent may enter his/her name, address, contact information and area(s) of speciality. Foreign manufacturers many then search the information to find a potential US Agent. The information in the database will not be reviewed by FDA and should not be interpreted as endorsing any person on the list, or as suggesting that the person is particularly trained or qualified to act as a United States agent.	Frequently as items become available
X-Ray Assembler Data	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

Updated 11/13/2002

資料(3)-1-2

ヘッダーの Industry Assitance を検索したもの

Industry Assistance

Device advice	CDRH's self-service site for medical device and radiation emitting product information. Device Advice is an interactive system obtaining information concerning medical devices
Guidance documents	Documents prepared for CDRH staff, regulated industry and the public that relate to the processing, content, and evaluation of regulatory submissions; the design, production, manufacturing, and testing of regulated products; and inspection and enforcement procedures
Industry support	Technical and regulatory assistance to small manufacturers to help them comply with FDA's requirements for medical devices.
International issues	Activities involving the import and export of medical devices and international harmonization in the regulation of medical devices
Medical device reporting (MDR)	Process by which industry, importers, user facilities, and the public can inform the FDA of problems with medical devices
Obtaining market clearance / approval	Steps involved in getting a medical device to market including marketing, proper labeling and monitoring its performance once the device is on the market
Ombudsman	Investigates complaints from outside FDA, and facilitates the resolution of disputes between CDRH and the industry it regulates
Standards	Practices recognized by CDRH that can be used by Industry as part of the process of determining the "safety and effectiveness" of new medical devices
Third party review	Process allowing 510(k) submitters to use FDA-accredited third party review organizations ("Accredited Persons") in place of FDA's review for certain medical devices

Updated 9/30/2002

資料(3)-1-3

ＣＤＲＨ(Center for Devices and Radiollgical Health)の
ＦＯＩ(Freedom of Information)による
事業所登録ファイルと機器リスト

Center for Devices and Radiological Health (CDRH) Freedom of Information (FOI) Releasable Establishment Registration and Device Listing Files

Establishment Registration and Medical Device Listing

Section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that all establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution in the United States register their establishments with the Food and Drug Administration (FDA). The term "device" includes all in-vitro diagnostic products and in-vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act (42 U.S.C. 262). Form FDA 2891 is used to register an establishment.

Section 510 of the Federal Food, Drug, and Cosmetic Act requires both domestic and foreign manufacturers to list their devices with FDA if the devices are in commercial distribution in the United States. Devices are listed by their classification name on form FDA 2892. The proprietary and common or usual name of the device(s) must be submitted to FDA upon request. In addition, manufacturers must maintain a historical listing file of labeling and advertisements in accordance with Title 21 Code of Federal Regulations (CFR) 807.31.

Neither registration nor listing constitutes FDA clearance or approval for marketing or commercial distribution in the U.S. Unless the device is exempt, a premarket notification submission [510(k)] or a premarket approval application (PMA) is required before commercial distribution commences. Registration of a device establishment or submission of device listing does not in any way denote approval of the establishment or its products by FDA. Any labeling or other representation that creates an impression of official FDA approval because of registration or listing is misleading and constitutes misbranding as referenced in section 301 of the FD&C Act and 21 CFR 807.39. For example, you may not show the FDA registration number or owner operator number on your labeling or advertising material.

Releasable Establishment Registration and Device Listing Files

The Medical Device Establishment Registration Master File contains the required information submitted by owner/operators of medical device establishments in accordance with Section 510 of the Federal Food, Drug and Cosmetic Act. A Search Mechanism is now available for Establishment Registration information and Device Listing information.

This information consists of three files. The three files are linked based on the Establishment Registration Number. You can download any or all of the following zipped files. Information about how to unzip these files is available.
The general steps are:

1. uncompress the file with WinUnzip, PKUnzip, or other utility;
2. rename file: filename.lis to filename.txt.
3. If the file is to be imported into a database, the end-of-record marker is the ~ symbol

A file description for each file is listed below along with an explanation of some of the codes used in the file. These files are replaced monthly, usually on the 5th of each month. File sizes are approximate.

File 1. Registration – Detailed information on each registered establishment: reglstre.zip
(compressed file size = 2700 KB; uncompressed file size = 10600 KB)

File 2. Registration Tradename – Other Trading names for registered establishments: regtrade.zip
(compressed file size = 91KB; uncompressed file size = 255KB)

File 3. Device Listing – Device listings submitted by registered establishments: listing.zip
(compressed file size = 2800 KB; uncompressed file size = 14400 KB)

The Medical Device Establishment Registration Master File is also sent out quarterly to:

U.S. Department of Commerce
National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

File Descriptions

Note: The file format was revised as of 4/5/02. New fields containing US Agent information have been added. The format is a delimited file (delimited by a | or "pipe"). A | or "pipe" is a character that marks the end of a field. The end of each record is marked by a paragraph marker or ¶. The length of each field in the data is variable. The maximum length for each field is shown in the table below. The names of the files have remained the same.

File 1. Registration

Field Description	Maximum Length
Establishment Registration Number (*)	10
Establishment Name	50
Establishment Street 1	30
Establishment Street 2	30
Establishment City	30
Establishment State Code	2
Establishment Zip Code	5
Establishment Zip Code Extension	4
Establishment Country Code	2
Establishment Operation Codes	16
Owner/Operator Number	7
Owner/Operator Name	50
Owner/Operator Street 1	30
Owner/Operator Street 2	30
Owner/Operator City	30
Owner/Operator State Code	2
Owner/Operator Zip Code	5
Owner/Operator Zip Code Extension	4
Owner/Operator Country Code	2
Official Correspondent Firm Name	50
Official Correspondent Street 1	30
Official Correspondent Street 2	30
Official Correspondent City	30
Official Correspondent State Code	2
Official Correspondent Zip Code	5
Official Correspondent Zip Code Extension	4
Official Correspondent Country Code	2

Establishment Status Codes	1
Year of Most Recent Initial or Annual Registration	6
Owner/Operator Phone Number	21
Official Correspondent Phone Number	20
Official Correspondent Name	45
USAgent Organization Name	50
USAgent Division Name	50
USAgent Street 1	30
USAgent Street 2	30
USAgent City	30
USAgent State Code	2
USAgent Zip Code	5
USAgent Zip Code Extension	4
USAgent Agent Name	65
USAgent Organizational Title	50
USAgent Phone Number	18
USAgent Fax Number	18
USAgent E-Mail Address	50
End of Record Marker	

File 2. Registration Tradename

Field Description	Maximum Length
Establishment Registration Number (*)	10
Trade Name	50
Filler	3

File 3. Device Listing

Field Description	Maximum Length
Medical Specialty Code	2
Product Code	3
Classification Name	120
Device Class	1
Regulation Number	8

Common/Generic Device Name	80
Proprietary Device Name	60
Owner/Operator Number	7
Owner/Operator Name	80
Establishment Registration Number (*)	10
Registered Establishment Name	40
Listing Operation Codes	10
Date of Listing	6
Listing Status Code	1
Filler	8

Establishment Operation Codes for Registration File and Listing Operation Codes for Device Listing File

Each registered establishment may perform up to eight operations, which are coded in the "Establishment Operation Codes" and "Listing Operation Codes" fields as follows:

AA Initial Distributor
CA Certifying Agent
DD Domestic Distributor
FL Unregistered Foreign Lister
ME Contract Manufacturer
MM Manufacturer
MP Private Label Manufacturer
MR Remanufacturer
MS Specification Developer
MX Rebuilder/Refurbisher
OT Contract Sterilizer
RR Repackager/Relabeller
TD Tentative Domestic Distributor
UU U.S. Designated Agent

Establishment Status Codes for Registration File

A Active
D Preproduction – Foreign
R Requested Preproduction – U.S.
P Active; awaiting assignment of registration number
T Tentatively out of business
B Tentatively back in business
L Unregistered foreign firm which has listed devices

Listing Status Codes for Device Listing File

A Active
D Deleted (firm no longer making produot)
P Pending listing
O Out of business

T Site Tentatively Out of business

Medical Specialty Codes for Device Listing File

AN Anesthesiology
CV Cardiovascular
CH Clinical Chemistry
TX Clinical Toxicology
DE Dental
EN Ear, Nose, Throat
SU General and Plastic Surgery
HO General Hospital
GU Gastroenterology/Urology
HE Hematology
IM Immunology
MI Microbiology
NE Neurology
OB OB-GYN
OP Ophthalmic
OR Orthopedic
PA Pathology
PM Physical Medicine
RA Radiology

(*) If the Establishment Registration Number is less than 7 characters in length it is not an official Establishment Registration Number but is used only for linking information in the Establishment and Device listing files. Official Establishment Registration Numbers may be either 7 or 10 characters in length.

Updated 9/13/02

資料(3)-1-4

ＰＭＡ(Premaket Approvals)に関する情報

Information on Premarket Approval Applications

General Information

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury . Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices.

An approved Premarket Approval Application (PMA) — like an approved New Drug Application (NDA) — is, in effect, a private license granted to the applicant for marketing a particular medical device. A Class III device that fails to meet PMA requirements is considered to be adulterated under Section 501(f) of the act and cannot be marketed. Premarket approval requirements apply differently to preamendments devices, postamendments devices, and transitional Class III devices.

A preamendments device is one that was in commercial distribution before May 28, 1976, the enactment date of the Medical Device Amendments. Manufacturers of Class III preamendments devices are not required to submit a PMA until 30 months after the promulgation of a final classification regulation or until 90 days after the publication of a final regulation requiring the submission of a PMA, whichever period is later. FDA may allow more than 90 days after promulgation of a final rule for submission of a PMA.

A postamendments device is one that was first distributed commercially on or after May 28, 1976. Postamendments devices that FDA determines are substantially equivalent to preamendments Class III devices are subject to the same requirements as the preamendments devices. FDA determines substantial equivalence after reviewing an applicant's premarket notification submitted in accordance with Section 510(k) of the act. Postamendments devices determined by FDA to be not substantially equivalent to either preamendments devices or postamendments devices classified into Class I or II are "new" devices and fall automatically into Class III. Before such devices can be marketed, they must have an approved premarket approval application or be reclassified into Class I (general controls) or Class II (standards).

Class III transitional devices and "new" devices (described in the paragraph above) are automatically classified into Class III by statute and require premarket approval by FDA before they may be commercially distributed. Applicants may either submit a PMA or Product Development Protocol (PDP), or they may petition FDA to reclassify the devices into Class I or Class II. Clinical studies in support of a PMA, PDP, or a reclassification petition are subject to the investigational device exemption (IDE) regulations. (For further details on these regulations, refer to 21 CFR 812 for general devices or 21 CFR 813 for intraocular lenses.)

New section 515 (d)(6) of the act added by the FDA Modernization Act of 1997, provides that PMA supplements are required for all changes that affect safety and effectiveness unless such change involves modifications to manufacturing procedures or method of manufacture. These types of manufacturing changes require a 30-day Notice or, where FDA finds such notice inadequate, a 135-day PMA supplement.

Requesting Administrative Review of CDRH's Decision to Approve a Premarket Approval (PMA) Application or a Notice of Completion for a Product Development Protocol *

As of January 30, 1998, FDA discontinued publication of individual PMA approvals in the Federal Register (Final Rule in Federal Register Vol 63 No. 20, Friday January 30, 1998, pg 4571). Instead, FDA will notify the public of its decision to approve a PMA by making available, via FDA's CDRH Internet HomePage (see http://www.fda.gov/cdrh/pmapage.html#monthly), a summary of the safety and effectiveness data upon which the approval is based. Written requests for this information can also be made to the Dockets Management Branch at the addressed identified below.

The 30-day period to submit petitions for administrative review will begin on the day the summary information is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Petitioners may, at any time on or before the 30th day, file with the Dockets Management Branch two copies of each petition and supporting data and information, identified with the name of the device and appropriate docket number. Petitions for administrative review must be submitted to:

The Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
5630 Fishers Lane, Room 1061, HFZ-305
Rockville, Maryland 20852
Telephone (301) 827-6860
Fax (301) 827-6870

Received petitions may be seen in the office above between 9 a.m. and 4p.m., Monday through Friday.

Section 515(d)(4) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve a PMA application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

* Under 21 CFR 814.19 a class III device for which a PDP has been declared completed by FDA is considered to have an approved PMA.

Searching The Releasable PMA Database

The PMA database may be searched by a variety of fields. A search query will produce information from the database in the following format:

- Classification Name
- Generic Name
- Applicant
- PMA Number
- Supplement Number
- Trade Name
- Date Received
- Decision Date
- Product Code
- Advisory Committee
- Supplement Type
- Supplement Reason
- Expedited Review Granted (Y/N)
- Approval Order Statement

PMA/PDP Files for Downloading

You can download the following zipped file, pmalist.zip, which contains information about the releasable PMA's. Information about how to unzip this file is available. These files are replaced monthly usually on the 5th of each month. In addition there is a file description and an explanation of some of the codes used in the file.You can also download or search the Product Code Classification Database which contains medical device names and associated information.

Monthly PMA Listings (in standard text format)

The monthly listing contains information regarding decisions for PMAs, PDPs, Supplements, and Notices. The date of the decision and application information such as address, device trade name, indication (in the case of an original or panel track supplement approval) or the nature of the change are provided. In addition, a table of summary statistics are provided for the numbers of submissions and review times.

2002 Monthly PMA Listings

	November	October
September	August	July
June	May	April

2001 Monthly PMA Listings

December	November	October
September	August	July
June	May	April

March	February	January

2000 Monthly PMA Listings

December	November	October
September	August	July
June	May	April
March	February	January

1999 Monthly PMA Listings

December	November	October
September	August	July
June	May	April
March	February	January

1998 Monthly PMA Listings

December	November	October
September	August	July
June	May	April
March	February	January

1997 Monthly PMA Listings

December	November	October
September	August	July
June	May	April
March	February	January

1996 Monthly PMA Listings

December	November	October
September	August	July
June	May	April
March	February	January

1995 Monthly PMA Listings

December	November	October
September	August	July
June	May	April
March	February	January

1994 Monthly PMA Listing

Other Resources

- "Real-Time" Program for PMA Supplements
- Fax Form for Real-Time PMA Supplement Applications
- Modifications To Devices Subject to Premarket Approval – The PMA Supplement Decision Making Process
- PMA Transformation Team Home Page

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