REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

TO NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR)
WASHINGTON, DC 20408

LEAVE BLANK (NARA use only)
JOB NUMBER: N1-088-08-1
DATE RECEIVED: 4/17/08

1 FROM (Agency or establishment)
Department of Health and Human Services

2 MAJOR SUBDIVISION
Food and Drug Administration (FDA)

3 MINOR SUBDIVISION
Center for Devices and Radiological Health (CDRH)

4 NAME OF PERSON WITH WHOM TO CONFER	5 TELEPHONE
Seung Ja Sinatra FAX 301-594-0060	(301) 827-4274

NOTIFICATION TO AGENCY

In accordance with the provisions of 44 U S C 3303a the disposition request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10

DATE	ARCHIVIST OF THE UNITED STATES
5/14/08	Michael J. Kurtz

6 AGENCY CERTIFICATION

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal on the attached 11 page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified; and that written concurrence from the General Accounting Office, under the provisions of Title 8 of the GAO Manual for Guidance of Federal Agencies,

☑ is not required, ☐ is attached; or ☐ has been requested.

DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
4/19/2008		HHS Records Officer

7 ITEM NO	8 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10 ACTION TAKEN (NARA USE ONLY)
	Unless specifically stated otherwise in the description or the retention, all items are media-neutral and apply to paper, electronic, microform, or other media in which records may exist SEE attached sheet CDRH Program Records Seung Ja Sinatra - FDA Records Officer — Date: 7/31/06 Ann Wion - FDA Office of the Chief Counsel — Date: 3/13/08		

Center for Devices and Radiological Health (CDRH) Program Records

File Code: Prefix = CDRH

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
1		**Program Management**	
1.1	1500	**MDUFMA Small Business Qualification Certification Records.** Small Business Qualification Certification - Qualification of a firm as a small business under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the Food and Drug Administration Amendments Act of 2007) Includes qualification certification forms and supporting documentation **Disposition: TEMPORARY.** Cutoff at end of the calendar year in which certification has been issued or denied. Delete/destroy 3 years after cutoff	**New**
2	2000	**Device PreMarket Activities**	
2.1	2100	**Classification and Reclassification Petition Files.** Classification identifies the level of regulatory control that is necessary to provide reasonable assurance of the safety and effectiveness of a medical device Per the 1976 Medical Device Amendments (MDA), it identifies, unless exempt, the regulatory process (either Premarket Notification (510(k)) or Premarket Approval (PMA)) that must be completed to lawfully market a device Includes duplicate copies of the Advisory Panel transcripts, petitions, final rules, public inquiries on specific classifications and FDA responses, whose records copies are maintained in the Dockets Branch and disposed of in accordance with Dockets records retention schedules Also includes records copies of materials related to classification and reclassification petition files, such as review notes, FDA-initiated rulemaking documents, records relating to the establishment of priority ranking for device standard development Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations **Disposition: TEMPORARY.** Cutoff at the end of the calendar year after final action is completed or product is withdrawn from the market. Delete/Destroy when no longer needed for business and regulatory purposes, or 20 years after cutoff, whichever is later "	**Supersedes K-13 NC 1-88-83-3**

2.2 2200 **513(g) Information Requests.** **Supersedes**
Information requests and Agency responses under section 513(g) of the FD&C Act as to which class a device has been assigned and the requirements applicable to the subject device and related records **K-18 NC 1-88-83-3**

Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after final action is completed. Delete/destroy when no longer needed for business and regulatory purposes, or 25 years after cutoff, whichever is later

2.3 2300 **Investigational and Pre-Investigational Device Exemptions (IDEs and PIDs).** **Supersedes**
An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data to support a Premarket Approval (PMA) application or a Premarket Notification (510(k)) submission to FDA. **K-19 NC 1-88-83-3**
The Pre-Investigational Device (PID) Exemption allows for the submission of preliminary information for comments by CDRH before submitting a formal IDE application
May include applications, supporting data, and FDA evaluations and approval decisions, with supporting material, made under Section 520(g) of the FD&C Act.

Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

Note: Record copies are maintained in the electronic records repository. Paper copies of scanned records may be destroyed upon verification according to GRS 20, item 2a4

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after final action is completed Delete/destroy when no longer needed for business and regulatory purposes, or 20 years after cutoff, whichever is later

2.4 2400 **PreMarket Approval Applications (PMAs).** **Supersedes**
Includes documentation of the FDA scientific and regulatory review process to evaluate the safety and effectiveness of Class III medical devices requiring a PMA application under section 515 of the FD&C Act May include alternate application forms such as Humanitarian Device Exemption (HDE), modular PMA, Product Development Protocol (PDP), and NDA forms 5 and 6 or supplements. **K-20, K-22 NC 1-88-83-3**
The records may include product information, test data, manufacturers' information, patient report forms, patient labeling, human factors reviews, FDA responses and related records

Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

Records copies of FDA approval and summaries of device safety and effectiveness data are maintained by the Dockets Branch and are also available on the Internet for public access These are disposed of in accordance with Dockets records retention schedules

Note Record copies are maintained in the electronic records repository. Paper copies of scanned records may be destroyed upon verification according to GRS 20, item 2a4

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after final action is completed or product is withdrawn from the market. Delete/Destroy when no longer needed for business and regulatory purposes, or 30 years after cutoff, whichever is later

2 4 1 2410 Monthly Listings of Approved PMAs and 510 ks **New**
Includes monthly listings of medical device premarket approval applications (PMAs) approved by CDRH that are published on the CDRH Internet site for public access.

Disposition: TEMPORARY.
Delete when no longer needed for public access.

2.5 2500 PreMarket Notification (510(k)). **Supersedes K-23 NC 1- 88-83-3**
Includes PreMarket Notifications (510(k)) submitted to FDA to demonstrate that a device is substantially equivalent to a legally marketed device that is not subject to PreMarket Approval (PMA)

May include correspondence and other documents received from persons and manufacturers seeking to introduce a medical device on the market, FDA evaluations and approval decisions made under Section 510(k) of the FD&C Act, patient labeling, human factor reviews, and other related materials.

Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

Note Record copies are maintained in the electronic records repository Paper copies of scanned records may be destroyed upon verification according to GRS 20, item 2a4

Disposition: TEMPORARY.

Cutoff at the end of the calendar year after final action is completed or product is withdrawn from the market. Delete/Destroy when no longer needed for business and regulatory purposes, or 20 years after cutoff, whichever is later

2.6 2600 Medical Device Master Files (MAF). **New**

Includes case files used to provide company-specific manufacturing or process information that can be referenced as part of an PMA, 510k, IDE, HDE or another MAF (Referencing Application) Files may include the records submitted by the MAF holder containing information regarding manufacturing and controls for devices as well as additional submissions from the MAF holder, FDA reviews and correspondence with the applicant.

Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

Note Record copies are maintained in the electronic records repository Paper copies of scanned records may be destroyed upon verification according to GRS 20, item 2a4

Disposition: TEMPORARY.
Delete/Destroy when no longer needed for administrative, business or reference purposes, whichever is the latest.

2.7 2700 PreMarket Tracking Systems (PTS). **New**

Tracks CDRH premarket review and approval activities in the following modules, but not limited to.
PreMarket Approval Application (PMAs)—Tracks evaluation/approval activities regarding Class III medical devices,
PreMarket Notifications (510(k))—Tracks 510(k)s,
Humanitarian Device Exemptions (HDEs)—Tracks review/approval of HDE applications for Humanitarian Use Devices (HUD),
Investigational Device Exemptions (IDEs)—Tracks IDE review processes for investigational devices, and
Product Development Protocols (PDPs)—Tracks PDP review process
A tool such as Center Tracking System is used to track work flow and work status management
Became operational in early 1990s Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

2.7 1 2710 PTS Data Files

Data fields vary depending on each module in the PTS Representative data include classification name, generic name, applicant, PMA number, trade name, date received, decision date, product code, Advisory Committee, supplement number/type/reason, expedited review granted (Y/N), approval order statement, summary/statement/purged Indicator,

summary or statement, and other related information

Disposition: TEMPORARY.
Cutoff at the end of the calendar year after final action is completed or product is withdrawn from the market Delete/destroy when no longer needed for business, regulatory, trend analysis or reference purposes, or 30 years after cutoff, whichever is the latest If data are migrated into a new system, delete/destroy after the verification of successful data migration

2 7 2 2720 Cumulative Lists of Approved PMAs and 510ks Output Records.
Includes electronic list files created monthly and maintained after files are moved to the CDRH mainframe

Disposition: TEMPORARY
Cutoff after file is created and moved to the mainframe. Delete 30 days after cutoff If copies become part of another records series, apply disposition authorized for that series.

~~2 7 3 2730 Other Output Records.~~ **GRS 20,**
~~Includes ad-hoc and status reports.~~ Items 4, 6, 7, 12 and 16

~~For reports produced for use in management reports such as annual reports and monthly scorecard reports, apply disposition authorized for appropriate records series~~

~~**Disposition: TEMPORARY.**~~
~~Destroy/delete when superseded or obsolete, or when no longer needed for reference, whichever is the latest~~

3 3000 Device PostMarket Activities

3.1 3100 PostMarket Surveillance Study Files. **New**
Postmarket surveillance is a tool that FDA can use to gain information about a device after it is marketed Includes surveillance plans identifying the manner in which manufacturers will collect information under section 522 of the FD&C Act, amendments that may be required to address deficiencies in the plan; supplements for the interim and final reports on the conduct of the surveillance plan or for any proposed changes and responses to requests for information, signed review memoranda, FDA decision letters, correspondence with the manufacturer and other related records Records date back to 1990

Certain records contain trade secret and confidential commercial information that may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations
Note. Record copies are maintained in the electronic records repository Paper copies of scanned records may be destroyed upon verification according to GRS 20, item 2a4

Disposition: TEMPORARY.

Cutoff annually at end of the calendar year after case is closed or completed. Delete/destroy 30 years after cutoff or when no longer needed for trend analysis or reference purposes, whichever is the latest

3.2 3200 **PostMarket Surveillance Study Tracking System (PSS) Data Files.**
Facilitates review processes of postmarket studies mandated for certain medical devices, tracks both Required/Discretionary and Postmarket Surveillance study submissions It became operational in 1993

Certain records contain trade secret and confidential commercial information that may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

Includes data fields such as document number, product code, product study key, decision code, document type and other related data.

Disposition: TEMPORARY.
Cutoff annually at end of the calendar year after case is closed or completed Delete/destroy 30 years after cutoff or when no longer needed for trend analysis or reference purposes, whichever is the latest

4 4000 [reserved for Device Compliance Activities]

5 CDRH Core Systems

6 6000 Radiological Health

6.1 6100 **Electronic Products Reports** **Supersedes X-7, X-12 NC 1-88-78-1**
Reports required by Title 21 of the Code of Federal Regulations, Part 1002 Includes product reports, supplemental reports, abbreviated reports, annual reports, accidental radiation occurrence reports and other related records. Receives approximately 6000 reports per year

Certain records contain trade secret and confidential commercial information hat may not be publicly released, disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations

Note. Record copies are maintained in the electronic records repository Paper copies of scanned records may be destroyed upon verification according to GRS 20, item 2a4.

Disposition: TEMPORARY.
Cutoff at end of the fiscal year after final action Delete/destroy 10 years after cutoff, or when FDA determines that they are no longer needed for administrative, legal, audit or other operational purposes, whichever is latest

6.2 6200 Electronic Product Postmarket Records

Incoming and outgoing correspondence, telephone communications, memoranda, and other information exchanged with manufacturers and others related to Electronic Product Radiation Control.

6.2.1 6210 Exemption Requests and Variance Requests. **Supersedes X-9 NC 1-88-78-1**

Includes records copies of requests for reporting exemption or notification exemption, FDA response and other correspondence with supporting materials
Also includes duplicate copies of FDA response, requests for variance from standard and exemption requests (from report requirements, standard applicability, or notification of defect or noncompliance) whose records copies are maintained by the Dockets Branch and subject to Dockets' records retention schedules

Certain records contain trade secret and confidential commercial information hat may not be publicly released; disclosure is subject to the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and restrictions in other statutes and FDA's implementing regulations.

Note Record copies are maintained in the electronic records repository. Paper copies of scanned records may be destroyed upon verification according to GRS 20, item 2a4.

Disposition: TEMPORARY.
Cutoff at end of the fiscal year after final action Delete/destroy 10 years after cutoff or when no longer needed for business, whichever is later.

6.2.2 6220 Non-Compliance and Corrective Action Files.

Includes records copies of notifications of noncompliance or defect, corrective action plans, compliance and enforcement actions and other supporting materials.

6 2.2 1 6221 Records with No Action **Supersedes X-8 NC1-88-78-1**

Record copies are maintained in the electronic records repository
Paper copies of scanned records may be destroyed upon verification according to GRS 20, item 2a4.

Disposition: TEMPORARY.
Cutoff at end of the fiscal year after final action Delete/destroy 10 years after cutoff

6 2 2 2 6222 Records with Action **Supersedes X-8 NC1-88-78-1**

Record copies are maintained in the electronic records repository.
Paper copies of scanned records may be destroyed upon verification according to GRS 20, item 2a4

Disposition: TEMPORARY.
Cutoff at the end of the fiscal year after firm is out of business or product does not exist Delete/destroy 10 years after cutoff

6.3 6300 **Electronic Product Establishment Inspection Files.** **Supersedes X-15 NC 1-88-78-1**

Includes a complete set of original inspection reports and supporting documents resulting from inspections of non-medical electronic product manufacturers
Record copies are maintained in the electronic records repository. Paper copies of scanned records may be destroyed upon verification according to GRS 20, item 2a4.

Records copies of the inspection files of Medical electronic products are maintained in the field

6 3 1 6310 Inspection reports without problems

Disposition: TEMPORARY.
Cutoff at end of the fiscal year in which received Delete/destroy 10 years after cutoff.

6 3 2 6320 Inspection reports with problems.

Disposition: TEMPORARY.
Cutoff at the end of the fiscal year when firm is out of business or the product is not marketed Delete/destroy 10 years after cutoff

6.4 6400 **X-Ray Assembler Certification Reports Program.**

Includes program-related records and certification reports or forms (e g FDA Form 2579, etc) that are sent to FDA, within 15 days following the completion of an assembly by an assembler who installs one or more certified components of a diagnostic x-ray system The report is the assembler's certification that the components installed are of the type called for by regulations, and they were assembled, adjusted, and tested in accordance with the manufacturer's instructions and meet all applicable performance requirements

~~6.4.1 6410 **Program Administrative Records.**~~
~~Operational procedures, internal instructions, quality assurance reports, and related records~~

~~**Disposition TEMPORARY**~~
~~Cutoff when superseded or obsolete Transfer to FRC 1 year after cutoff Delete/destroy 6 years after cutoff~~

6.4.2 6420 **Certification Reports or Forms (e.g. FDA Form 2579).** **Supersedes 2A1 and 2A2 N1-088-03-2**

Original reports or forms sent to and maintained by the FDA District Field Offices

Disposition: TEMPORARY. Cutoff annually at end of the fiscal year after final action Delete/destroy 6 years after cutoff

6.4.3 6430 **X-Ray Assembler Certification Tracking Database Files.** **Supersedes 3A**

Data taken from certification reports or forms and any additional

information, notations, or analyses that are directly entered into the tracking database Includes data fields such as assembler's name, product, date assembled, and other related information. Also used for historical trend analysis. **N1-088-03-2**

Disposition: TEMPORARY.
Cutoff at end of the fiscal year after final action Delete or destroy 6 years after cutoff, or when FDA determines that they are no longer needed for administrative, legal, audit, or other operational purposes, whichever is the latest

6.5 6500 Laboratory Testing Records **Supersedes X-22 (NC 1-88-83-4), R-33 (NC 1-88-82-1)**

Source data, analytical worksheets, reports on results of tests performed on regulated radiological products by a laboratory such as Winchester Engineering and Analytical Center (WEAC) to determine product compliance with applicable standards, product safety and efficacy

Note. Record copies are maintained in the electronic records repository Paper copies of scanned records may be destroyed upon verification according to GRS 20, item 2a4.

Disposition: TEMPORARY.
Cutoff at end of the fiscal year in which test is completed and case is closed Delete/destroy 10 years after cutoff or when no longer needed for business, whichever is later.

6.6 6600 Nation-wide Evaluation of X-Ray Trends(NEXT) Files. **Supersedes X-18 (NC 1-88-79-2)**

Includes materials on monitoring X-ray use trends and X-ray exposure studies to evaluate public exposure and dose, determine radiation protection program effectiveness and identify areas needing greater attention It allows States to evaluate radiation protection progress

Disposition: TEMPORARY.
Cutoff at end of the fiscal year in which survey is completed. Destroy 30 years after cutoff, or when no longer needed for research or reference, whichever is later