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FDA U.S. Food and Drug Administration

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Medical Devices

Home > Medical Devices

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Glucose Testing Devices
Help control diabetes by monitoring blood sugar.

Hearing Aids
Learn about hearing loss and the benefits and safety of hearing aids.

CDRH FY 2010 Strategic Priorities
Priority areas of activity for the coming year.

Products and Medical Procedures
Approvals & Clearances, Home Use, Surgical, Implants & Prosthetics, In Vitro Diagnostics, more...

Medical Device Safety
Alerts & Notices, Recalls, Report a Problem, MedSun, Emergency Situations

Device Advice: Device Regulation and Guidance
How to Market a Device, Postmarket Requirements, Compliance, Importing & Exporting, more...

Science and Research (Medical Devices)
Chemistry & Materials Science, Solid & Fluid Mechanics, Imaging & Applied Mathematics, Electrical & Software Engineering, more...

News & Events (Medical Devices)
Medical Device News, Videos, Workshops & Meetings

Resources for You (Medical Devices)
Consumers, Health Care Providers, Regulated Industry

Search Medical Devices

Spotlight

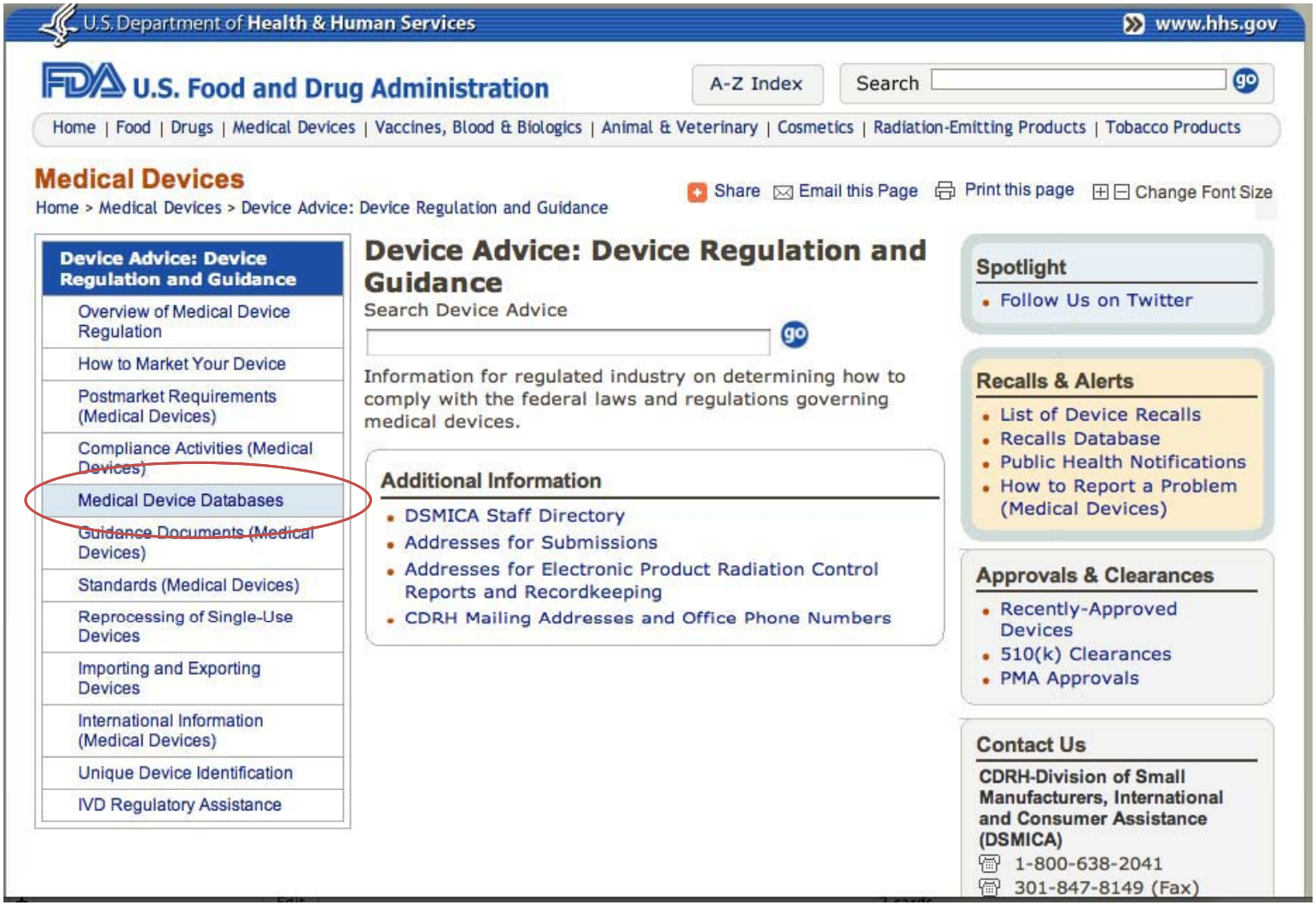
- CDRH Ombudsman Annual Report - Calendar Year 2009
- LASIK
- Breast Implants
- Personal Protective Equipment
- Radiation-Emitting Products

Recalls & Alerts

- Information About STERIS System 1
- List of Device Recalls
- Recalls Database
- Public Health Notifications
- How to Report a Problem (Medical Devices)

Approvals & Clearances

- FDA Approves First Percutaneous Heart Valve
- Recently-Approved Devices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Information for regulated industry on determining how to comply with the federal laws and regulations governing medical devices.
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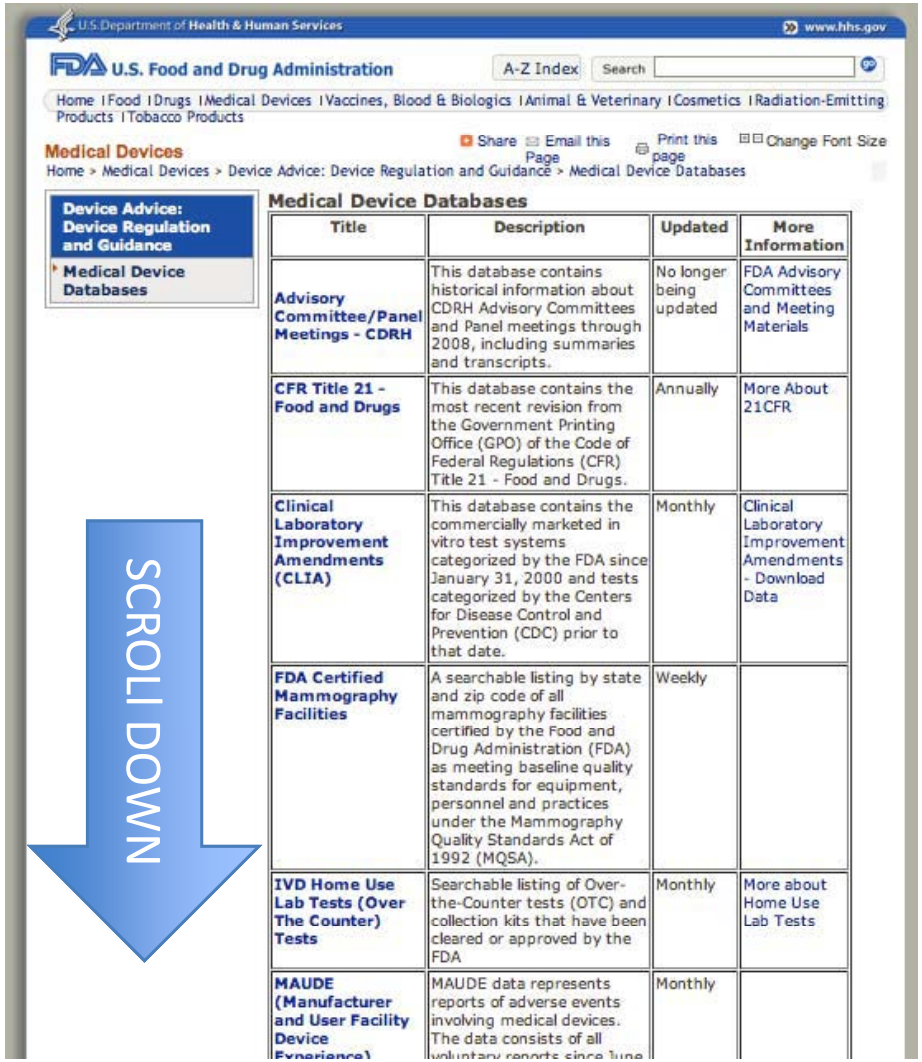
Contact Us
CDRH-Division of Small Manufacturers, International and Consumer Assistance (DSMICA)
1-800-638-2041
301-847-8149 (Fax)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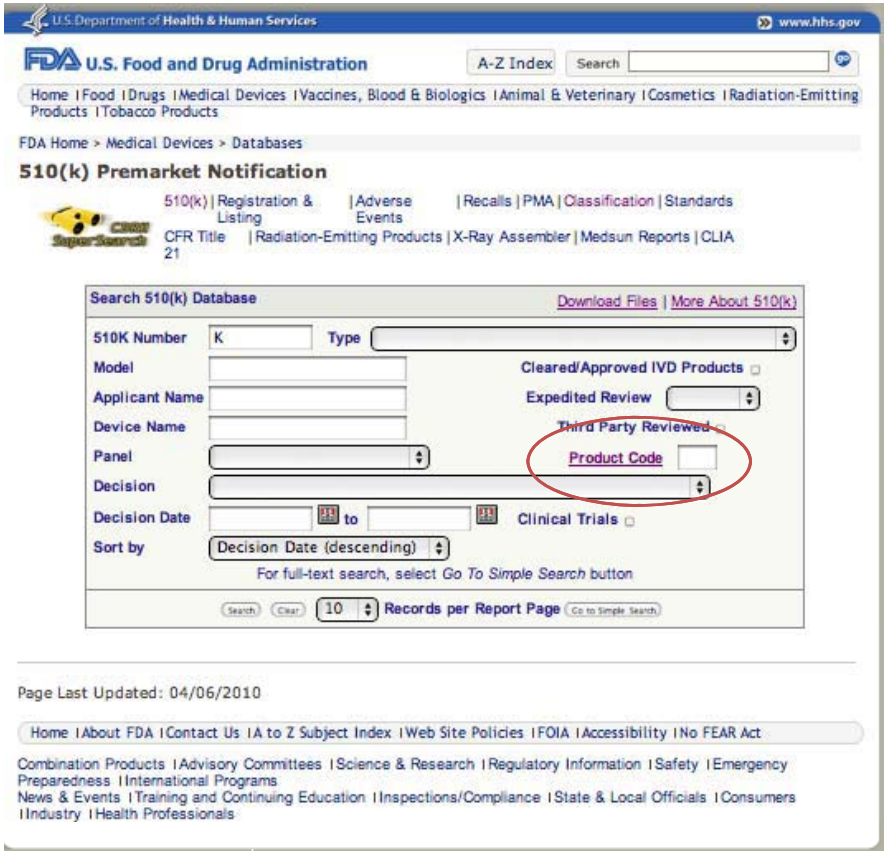
Advisory Committee/Panel Meetings - CDRH
This database contains historical information about CDRH Advisory Committees and Panel meetings through 2008, including summaries and transcripts.
No longer being updated
FDA Advisory Committees and Meeting Materials
CFR Title 21 - Food and Drugs
This database contains the most recent revision from the Government Printing Office (GPO) of the Code of Federal Regulations (CFR) Title 21 - Food and Drugs.
Annually
More About 21CFR
Clinical Laboratory Improvement Amendments (CLIA)
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.
Monthly
Clinical Laboratory Improvement Amendments - Download Data
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
IVD Home Use Lab Tests (Over The Counter) Tests
Searchable listing of Over-the-Counter tests (OTC) and collection kits that have been cleared or approved by the FDA
Monthly
More about Home Use Lab Tests
MAUDE (Manufacturer and User Facility Device Experience)
MAUDE data represents reports of adverse events involving medical devices. The data consists of all
Monthly

	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.		for the CDRH Releasable (Approved) PMAs
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 the web interface for more recent records. The database is updated monthly.	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	More about Product Code Classification Database
Radiation-emitting Electronic Product Codes	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.	Monthly	
Recalls of Medical Devices	This database contains a list of classified medical device	Frequently as items	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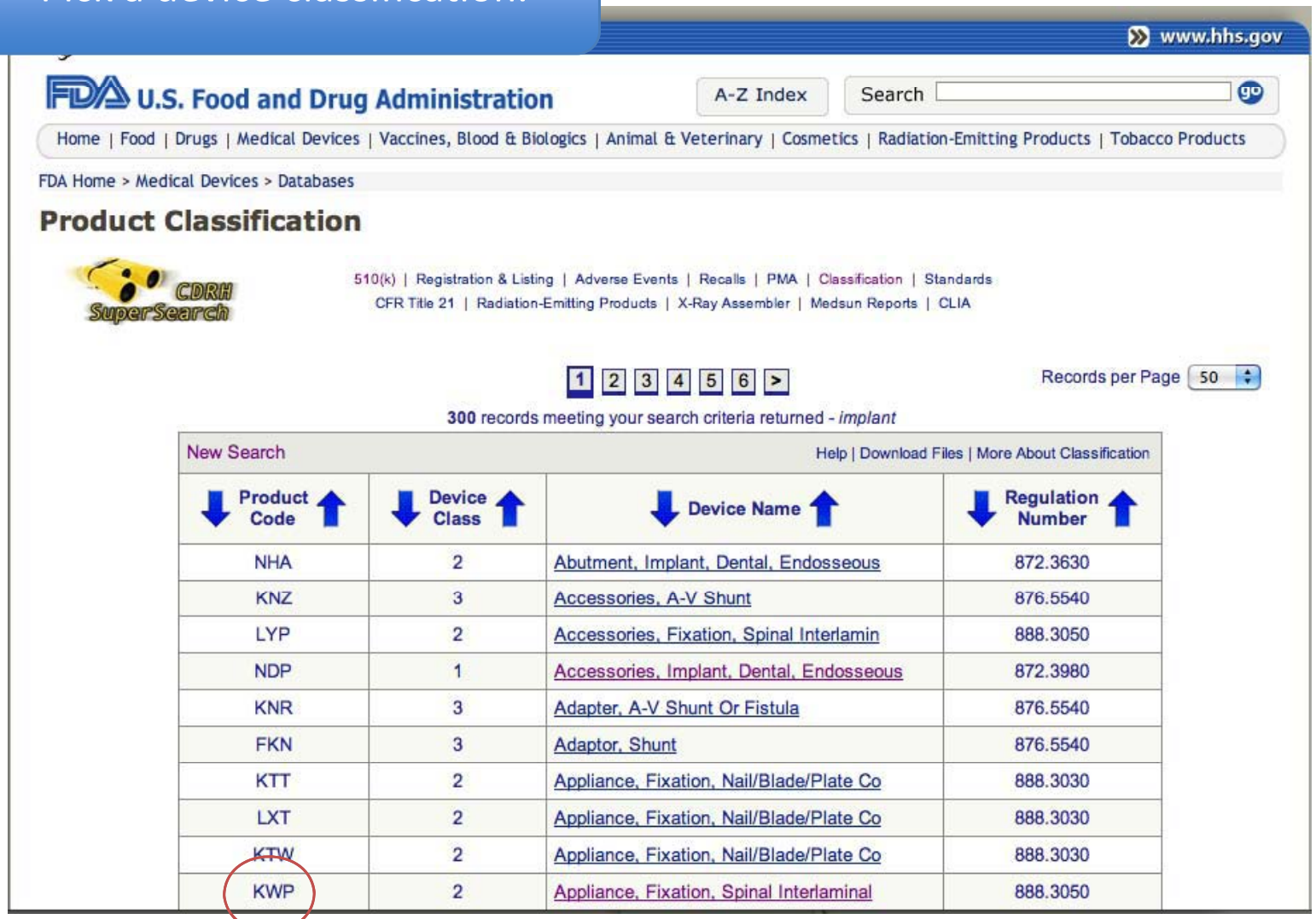
Pick a device classification.



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Product Classification

CDRH SuperSearch

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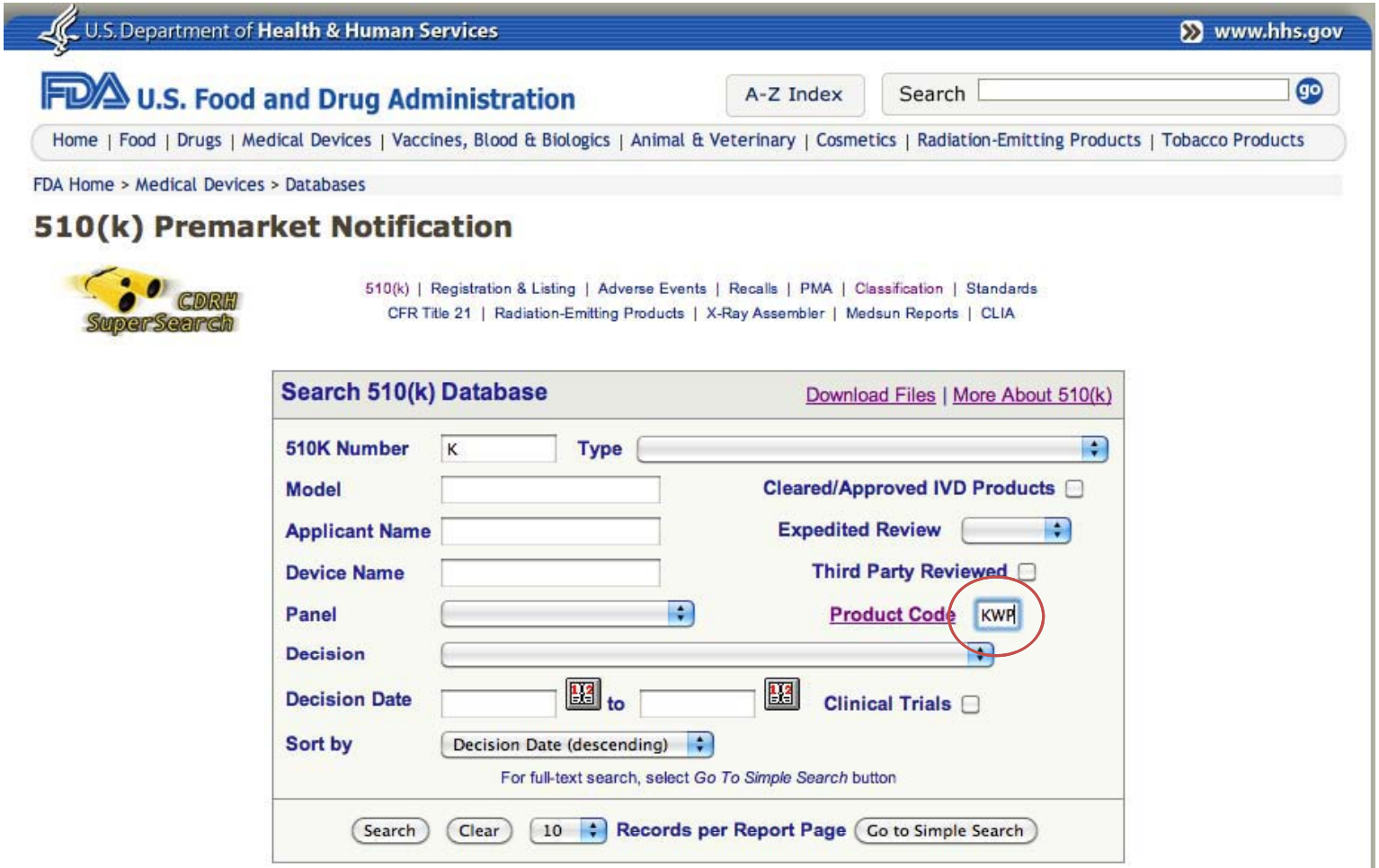
1 2 3 4 5 6 > Records per Page 50

300 records meeting your search criteria returned - *implant*

New Search | Help | Download Files | More About Classification

Product Code	Device Class	Device Name	Regulation Number
NHA	2	Abutment, Implant, Dental, Endosseous	872.3630
KNZ	3	Accessories, A-V Shunt	876.5540
LYP	2	Accessories, Fixation, Spinal Interlamin	888.3050
NDP	1	Accessories, Implant, Dental, Endosseous	872.3980
KNR	3	Adapter, A-V Shunt Or Fistula	876.5540
FKN	3	Adaptor, Shunt	876.5540
KTT	2	Appliance, Fixation, Nail/Blade/Plate Co	888.3030
LXT	2	Appliance, Fixation, Nail/Blade/Plate Co	888.3030
KTW	2	Appliance, Fixation, Nail/Blade/Plate Co	888.3030
KWP	2	Appliance, Fixation, Spinal Interlaminal	888.3050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Clinical Trials
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Decision Date (descending)
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510(k) Premarket Notification

500 records meeting your search criteria returned .
The number of records meeting your search criteria is greater than the system can return and is incomplete.
It is not possible to retrieve the missing records. Please narrow your search.

New Search

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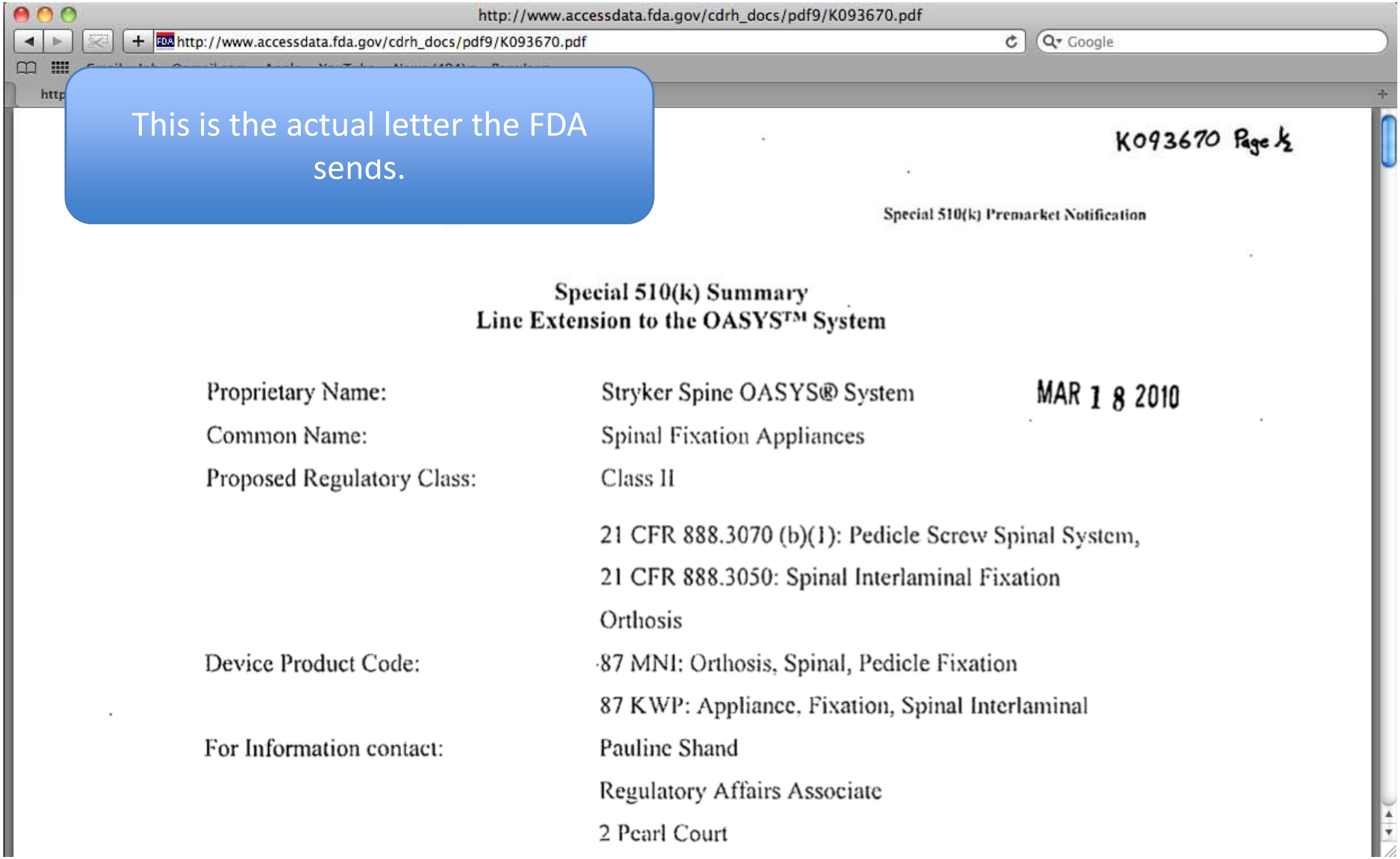
Device	Applicant	510(k)	Decision Date
Ldr Spine Usa Spine Tune Tl Spine System	Ldr Spine Usa	K100575	03/31/2010
Modification To: Oasys System	Stryker Spine	K093670	03/18/2010
Apex Spine System 5.50 Mm Titanium Rod &	Spinecraft, Inc.	K092825	03/16/2010
Romeo Posterior Osteosynthesis System	Spineart	K093936	03/11/2010
Synthes Matrix Mis Rods	Synthes (Usa)	K093668	03/09/2010
Pass Lp Spinal System	Medicrea Technologies	K100297	03/04/2010
Pioneer Posterior Cervico-Thoracic Syste	Pioneer Surgical Technology	K092295	02/19/2010
Revere Stabilization System	Globus Medical Inc.	K093294	02/17/2010
Zodiac Polyaxial Spinal Fixation System	Alphatec Spine, Inc.	K100138	02/17/2010
Any Plus Spinal Fixation System	Gs Medical Co., Ltd.	K091717	01/25/2010

510(k) Premarket Notification

New Search Back To Search Results

Device Classification Name	Orthosis, Spondyloisthesis Spinal Fixation
510(K) Number	K093670
Device Name	MODIFICATION TO: OASYS SYSTEM
Applicant	STRYKER SPINE 2 Pearl Court Allendale, NJ 07401 167
Contact	Pauline Shand
Regulation Number	888.3070
Classification Product Code	MNH
Subsequent Product Codes	KWP MNI
Date Received	11/27/2009
Decision Date	03/18/2010
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Special
Reviewed By Third Party	No
Expedited Review	No


http://www.accessdata.fda.gov/cdrh_docs/pdf9/K093670.pdf
http://www.accessdata.fda.gov/cdrh_docs/pdf9/K093670.pdf
Google
This is the actual letter the FDA sends.
K093670 Page ½
Special 510(k) Premarket Notification
Special 510(k) Summary
Line Extension to the OASYS™ System
Proprietary Name: Stryker Spine OASYS® System
MAR 1 8 2010
Common Name: Spinal Fixation Appliances
Proposed Regulatory Class: Class II
21 CFR 888.3070 (b)(1): Pedicle Screw Spinal System,
21 CFR 888.3050: Spinal Interlaminal Fixation
Orthosis
Device Product Code: 87 MNI: Orthosis, Spinal, Pedicle Fixation
87 KWP: Appliance, Fixation, Spinal Interlaminal
For Information contact: Pauline Shand
Regulatory Affairs Associate
2 Pearl Court

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

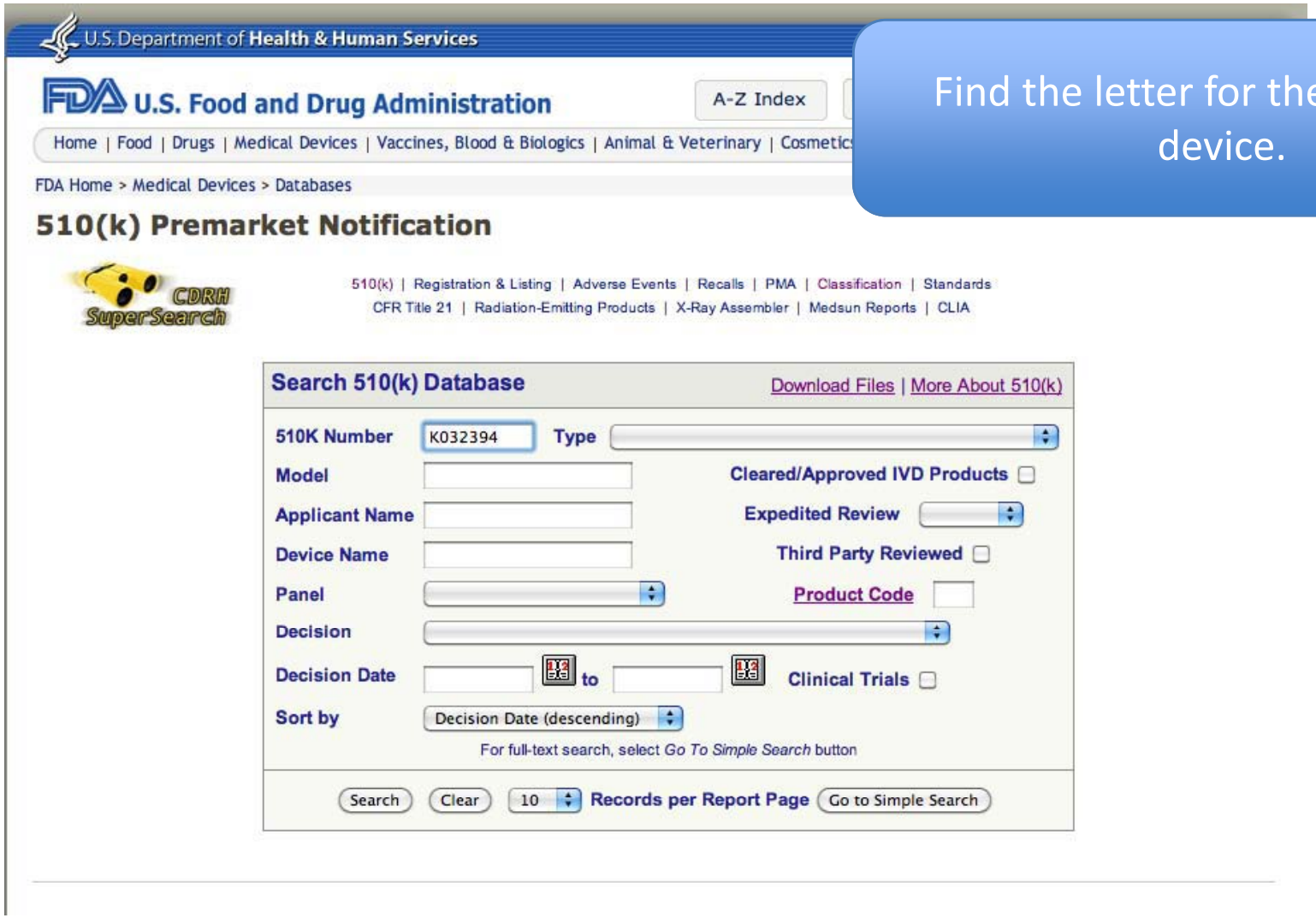
The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

The Stryker Spine OASYS® System can also be linked to the Xia® System, SR90D System and Xia® 4.5 Spinal System via the rod-to-rod connectors.

Statement of Technological Comparison:

Testing has demonstrated that the additional midline occiput plate, bone screws and Vitallium® rod have equivalent mechanical properties to the predicate OASYS® System K032394, K072568, and K052317. Both the new components and the existing system components are intended to address the same indications for use.

This is the predicate device.



Find the letter for the predicate device.

And continue the chain.

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Device Classification Name	Orthosis, Spinal Pedicle Fixation
510(K) Number	K032394
Device Name	STRYKER SPINE OASYS SYSTEM
Applicant	HOWMEDICA OSTEONICS CORP. 59 Route 17 South Allendale, NJ 07401 167
Contact	Karen Ariemma
Regulation Number	888.3070
Classification Product Code	MNI
Subsequent Product Code	KWP
Date Received	08/04/2003
Decision Date	02/20/2004
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

EC.710 D-Lab: Medical Technologies for the Developing World

Spring 2010