Institutional Review Board Responsibilities in making the Significant Risk and Non-significant Risk Device Determination

Marian Serge, RN

Nurse Consultant
Division of Bioresearch Monitoring
Office of Compliance
Center for Devices and Radiological Health

Topics

- Background
- Define SR and NSR device studies
- IRB Responsibilities
- What IRB's consider when making the SR/NSR determination
- Documentation of IRB determination
- How to find 510(k) and PMA labeling

Background

- Investigational Device Exemption (IDE) Regulation is found Title 21 CFR 812
  - Sponsor and IRB responsibilities for NSR device determination
- Why provide this information?
  - Improve IRB understanding of responsibility
  - Improve compliance with FDA regulation
- IRB serves as FDA surrogate for NSR device investigations
  - Providing initial and continuing review

Significant Risk Device Definition at 812

- Presents a potential serious risk to the health, safety, or welfare of a subject and is:
  - an implant; or
  - life-supporting or life-sustaining; or
  - of substantial importance in diagnosing, curing, mitigating, or treating disease or preventing impairment of human health

What is a Non-Significant Risk Device?

- One that does not meet the definition of a significant risk device

Who Decides Whether a Device is SR or NSR?

- Sponsors
  - Make the initial risk determination
  - Present the IRB with this information
- IRBs
  - Required to determine whether the NSR device study involves a SR or NSR device
- FDA
  - Available to help
  - Final arbiter

What are the Requirements in 21 CFR 812 for NSR Device Studies?

- Abbreviated requirements at 21CFR 812.2(b)
  - Labeling, IRB approval, informed consent, monitoring, record keeping, reports, and prohibition against promotion.
- NSR studies are considered to have an approved IDE therefore no formal IDE application to FDA is necessary
- Sponsors and IRBs do not have to advise FDA of NSR device studies
- IRBs must make a SR or NSR device determination for every NSR device study (21 CFR 812.66)

What is the sponsor's responsibility to the IRB for NSR device studies?

- Provide reviewing IRBs with a brief explanation of why the device is not a SR
- Any other information requested by the IRB
  - Description of device
  - Reports of prior investigations
  - Proposed investigational plan
  - Subject selection criteria
- Inform IRB if FDA determined the study to be NSR

IRB responsibilities for NSR device studies

- Review materials (see previous slide)
- Make risk determination
- Document determination in meeting minutes

Process to use when requesting FDA's assistance when making the risk determination

- See handout
  - Information to be submitted to FDA
  - Cover letter and reference line
  - Your address and contact info
  - 60 or fewer days to make the determination
  - CDRH letter with determination
  - CDRH contact person: Sheila.Brown@fda.hhs.gov

What Should IRBs Consider When Making the SR or NSR Determination?

For studies presented as NSR device studies, IRBs should consider:

- What is the basis for the risk?
  - Proposed use of device
- What is nature of harm that may result from the use of the device?
- Additional procedures
  - Potential harm from procedures

Let's Put This into Practice

Study of a change in a component of a device. For example: new leads, battery pack, or software of an approved pacemaker

- Basis for risk: Any change to a component is a change to the device itself
- This study is significant risk and requires IDE approval by FDA

More Practice

Study of a 510k, non-significant risk, daily wear lens device to be used as overnight lens. Design changes.

- A review of the proposed use and nature of harm reveals a potential for injury not normally seen with daily wear lens
- This study is significant risk and requires IDE approval by FDA

What Happens When the Sponsor and IRB Determination Disagree?

- If the IRB determines that a NSR device study involves a SR device
  - IRB must inform the clinical investigator and where appropriate the sponsor
  - Sponsors contact FDA for final risk determination
  - The study cannot start until sponsor obtains an IDE

What Happens When the IRB Agrees with the Sponsor's NSR Determination?

- If IRB determination of NSR agrees with sponsor's NSR
  - IRB can review the study using criteria at 21 CFR 56.111
  - The study may begin without notice to FDA or IDE application to FDA

How do IRBs Document the SR or NSR Determination?

- Write determination in minutes
  - Give reason for determination
- Lastly, maintain all materials reviewed

Approved devices used in research

How can IRBs find 510(k) or PMA approval orders and indications for use?

- **www.fda.gov**
- Click on Medical Devices
- Click on Device Advice
- Click on premarket notification 510(k)
- Click on premarket approvals (PMA)
- Complete 510(k) or PMA numbers

Edit View Favorites Tools Help

Back Search Favorites

http://www.fda.gov/ Go Links

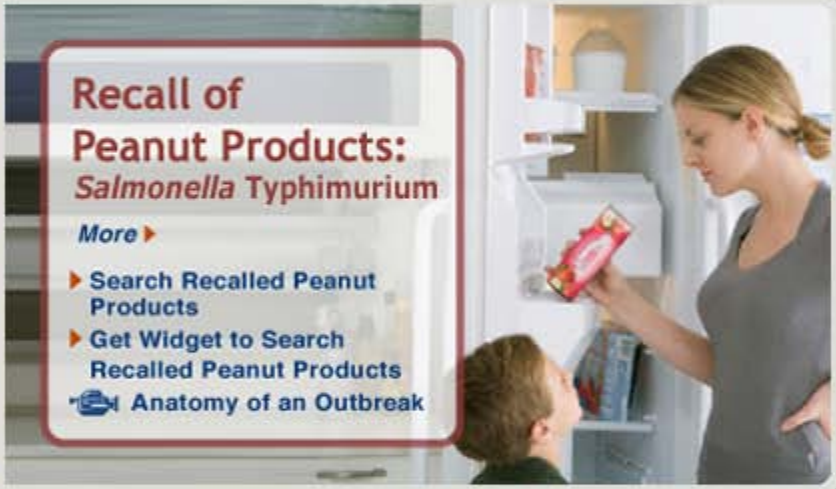
U.S. Department of Health & Human Services www.hhs.gov

U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

Search go

- Food
- Drugs
- Medical Devices
- Biologics, Blood & Vaccines
- Animal & Veterinary
- Cosmetics
- Radiation-Emitting Products
- Combination Products



A-Z Index

A B C D E F G H I
J K L M N O P Q R
S T U V W X Y Z #

Most Popular

- Melamine Contamination
- Licensed Vaccines
- Adverse Event Reporting System (AERS)
- Qualified Health Claims
- LASIK

Science & Research

- Modernizing the Critical Path Sciences
- Clinical Trials
- Pediatric Therapeutics
- Rare Diseases
- Toxicological Research

More Science & Research

In The Spotlight

Pistachio Product Recalls: *Salmonella*

More

Search Recalled Pistachio Products

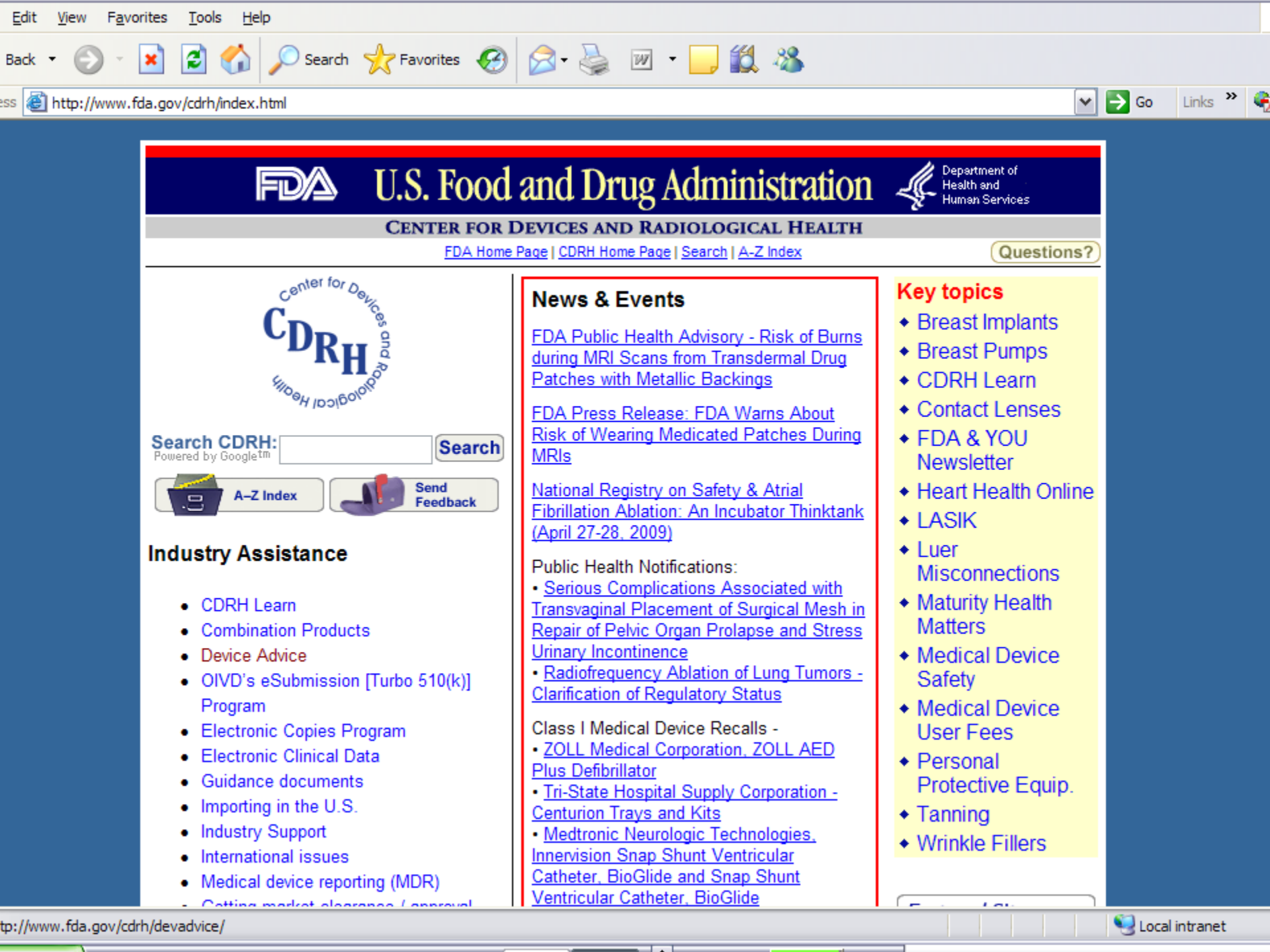
Spotlight Archive

Report a Problem

- Drugs, Medical Devices... (MedWatch)
- Food
- Vaccines
- All FDA Products

tp://www.accessdata.fda.gov/scripts/pistachiorecall/index.cfm

Local intranet


Edit View Favorites Tools Help
Back Search Favorites
http://www.fda.gov/cdrh/index.html
Go Links
FDA U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
FDA Home Page | CDRH Home Page | Search | A-Z Index
Questions?
Center for Devices and Radiological Health
CDRH
Search CDRH:
Powered by Google™
Search
A–Z Index
Send Feedback
Industry Assistance
CDRH Learn
Combination Products
Device Advice
OIVD's eSubmission [Turbo 510(k)] Program
Electronic Copies Program
Electronic Clinical Data
Guidance documents
Importing in the U.S.
Industry Support
International issues
Medical device reporting (MDR)
News & Events
FDA Public Health Advisory - Risk of Burns during MRI Scans from Transdermal Drug Patches with Metallic Backings
FDA Press Release: FDA Warns About Risk of Wearing Medicated Patches During MRIs
National Registry on Safety & Atrial Fibrillation Ablation: An Incubator Thinktank (April 27-28, 2009)
Public Health Notifications:
• Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence
• Radiofrequency Ablation of Lung Tumors - Clarification of Regulatory Status
Class I Medical Device Recalls -
• ZOLL Medical Corporation, ZOLL AED Plus Defibrillator
• Tri-State Hospital Supply Corporation - Centurion Trays and Kits
• Medtronic Neurologic Technologies, Innervision Snap Shunt Ventricular Catheter, BioGlide and Snap Shunt Ventricular Catheter, BioGlide
Key topics
Breast Implants
Breast Pumps
CDRH Learn
Contact Lenses
FDA & YOU Newsletter
Heart Health Online
LASIK
Luer Misconnections
Maturity Health Matters
Medical Device Safety
Medical Device User Fees
Personal Protective Equip.
Tanning
Wrinkle Fillers
tp://www.fda.gov/cdrh/devadvice/
Local intranet

evice Advice

Device Advice is CDRH`s self-service site for medical device and radiation emitting product information. It is an interactive system for obtaining regulatory information concerning medical devices.

edical Device Regulations

Resources	Premarket Information	Premarket Submissions	Postmarket Information
Overview of Regulations	Is Your Product Regulated?	Premarket Notification 510(k)	Establishment Registration
Workshops	Classify Your Device	Investigational Device Exemption (IDE) for Clinical Studies	Device Listing
Guidance Documents	How to Market Your Device	Premarket Approval (PMA)	Quality Systems for Manufacturing
CDRH Databases	510(k)/GMP Exemption	Humanitarian Device Exemption (HDE)	Medical Device Reporting for Adverse Events
Code of Federal Regulations	Device Labeling		Recalls/ Corrections and Removals
International Information			Importing Devices
Consumer Information			Exporting Devices
CDRH Learn			Medical Device Tracking
			Postmarket Surveillance Studies

adiation Emitting Products

elated Items Code)	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.	
remarket 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
remarket 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
roduct 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
adiation-emitting lectronic 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
ecalls of Medical Devices	This database contains a list of classified medical device recalls since November 1, 2002	Frequently as items become

Edit View Favorites Tools Help

Back Search Favorites

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Go Links

FDA U.S. Food and Drug Administration Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FDA Home Page | CDRH Home Page | Search | A-Z Index

Questions?

CDRH SuperSearch

510(k) | Registration & Listing | Adverse Events | PMA | Classification | CLIA

CFR Title 21 | Advisory Committees | Assembler | Recalls | Guidance | Standards

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)		

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

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

Database Updated 04/07/2009

Local intranet

Edit View Favorites Tools Help

Back Search Favorites

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Go Links

FDA U.S. Food and Drug Administration — Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FDA Home Page | CDRH Home Page | Search | A-Z Index

Questions?

CDRH SuperSearch

510(k) | Registration & Listing | Adverse Events | PMA | Classification | CLIA

CFR Title 21 | Advisory Committees | Assembler | Recalls | Guidance | Standards

Search 510(k) Database

Download Files | More About 510(k)

510K Number	K090023	**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)		

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

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

Database Updated 04/07/2009

Local intranet

510(k) Premarket Notification Database

Device Classification Name	Interferential Current Therapy
510(K) Number	K090023
Device Name	IF SERIES TRUE SINE INTERFERENTIAL STIMULATOR, MODEL: WL-2206B AND WL-2106E
Applicant	WELL-LIFE HEALTHCARE LIMITED 1fl, No.16, Lane 454 Jungjeng Rd. Yunghe City, Taipei County,
Contact	Jenny Hsieh
Classification Product Code	LIH
Date Received	01/05/2009
Decision Date	01/30/2009
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Neurology
Review Advisory Committee	Neurology
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Special
Reviewed By Third Party	No

510(K) Summary

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K090023 .

JAN 30 2009

1. Submitter's Identifications:

Company Name:	Well Life Healthcare Limited
Contact person:	Jenny Hsieh
Address:	1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City, Taipei County, Taiwan, R.O.C.
TEL No.:	886-2-2928-2112
Fax No.:	886-2-2928-1880
E-mail address:	jenny@welllifehealthcare.com.tw

2. Name of the Device:

IF series True sine interferential stimulator / Model: WL-2206B & WL-2106E.

3. Information of the 510(k) Cleared Device (Predicate Device):

2. Name of the Device:

IF series True sine interferential stimulator / Model: WL-2206B & WL-2106E.

3. Information of the 510(k) Cleared Device (Predicate Device):

WL-2206A2 (K060975).

4. Device Description:

The WL-2206B and WL-2106E are the device which generates the small true-sine pulses of electrical current. The generated current may be delivered to the patient skin and/or underlying nerves through the cable and electrode placed on skin.

5. Intended Use:

The device is an interferential stimulator with TENS indications used for symptomatic relief and management of chronic intractable pain.

In addition, the standard format for the statement of indications and contraindication for use are provided hereafter.

6. Substantial Equivalence Comparison

The WL-2206B and WL-2106E have output characteristics and controls that are identical to

VD 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
IAUDE (Manufacturer and ser Facility Device xperience)	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.	Monthly
IDR (Medical Device eporting)	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
HRIC (National Health elated 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
remarket 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
remarket 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

U.S. Food and Drug Administration

Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Search Premarket Approval (PMA) Database

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

Supplement Type

Sort by Decision Date (descending)

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

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

Database Updated 04/07/2009

U.S. Food and Drug Administration

Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Search Premarket Approval (PMA) Database

Help | Download Files | More About PMA

Applicant Name

Trade Name

Decision Date to

Notice Date to

Docket Number

Expedited Review

Product Code

PMA Number P070016

Advisory Committee

Cleared/Approved IVD Products

Supplement Type

Sort by Decision Date (descending)

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

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

Database Updated 04/07/2009

FDA U.S. Food and Drug Administration
Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

4 records meeting your search criteria returned - **PMANumber:** *P070016*

New Search — Help | Download Files | More About PMA

Trade Name	Applicant	PMA Number	Decision Date
ZENITH TX2 TAA ENDOV	Cook, Inc.	P070016 S003	01/27/2009
ZENITH TX2 THORACIC	Cook, Inc.	P070016 S001	11/26/2008
ZENITH TX2 TAA ENDOV	Cook, Inc.	P070016 S002	11/25/2008
ZENITH TX2 THORACIC	William Cook Europe	P070016	05/21/2008

Database Updated 04/07/2009

Note: this medical device has supplements. The device description may have changed. Be sure to look at the supplements to get an up-to-date view of this device.

Premarket Approval (PMA) Database

Trade Name	ZENITH TX2 THORACIC TAA ENDOVASCULAR GRAFT WITH THE H&LB ONE-SHOT INTRODUCTION SYSTEM
Classification Name	System, Endovascular Graft, Aortic Aneurysm Treatment
Applicant	WILLIAM COOK EUROPE APS
PMA Number	P070016
Date Received	07/02/2007
Decision Date	05/21/2008
Product Code	MIH [Registered Establishments with MIH]
Docket Number	08M0311
Notice Date	05/27/2008
Advisory Committee	Cardiovascular
Expedited Review Granted?	No
Information About:	Labeling, Approval Order, Summary Of Safety And Effectiveness

Approval Order Statement Approval for the zenith tx2 thoracic taa endovascular graft with the h&lb one-shot introduction system. This device is indicated for the endovascular treatment of patients with

enith® TX2® Thoracic TAA Endovascular Graft with the H&LB One-Shot™ troduction System – P070016

ued May 21, 2008

- Approval Order
- Summary
- Labeling
- Other Consumer Information

Updated July 3, 2008

Summary of Safety and Effectiveness Data (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Thoracic Endovascular Graft
Device Trade Name:	Zenith TX2® TAA Endovascular Graft
Applicant Name and Address:	William Cook Europe, ApS Sandet 6, DK 4632 Bjaeverskov, Denmark
Premarket Approval Application (PMA) Number:	P070016
Date of Panel Recommendation:	None
Date of Notice of Approval to Applicant:	May 21, 2008
Expedited:	Not applicable

II. INDICATIONS FOR USE

The Zenith TX2® TAA Endovascular Graft with the H&L-B One-Shot™ Introduction System is indicated for the endovascular treatment of patients with aneurysms or ulcers of the descending thoracic aorta having vascular morphology suitable for endovascular repair, including:

There is no Website for you to search for information about investigational devices (IDE) used in research. FDA holds that information confidential.

References

- FDA Information Sheets
  - http://www.fda.gov/oc/gcp/default.htm

Summary

- Distinction between significant risk (SR) and non-significant risk (NSR)
- Criteria IRB should use when making SR or NSR determination
- How to document IRB's determination of SR or NSR
- How to find 510(k) and PMA labeling

Questions