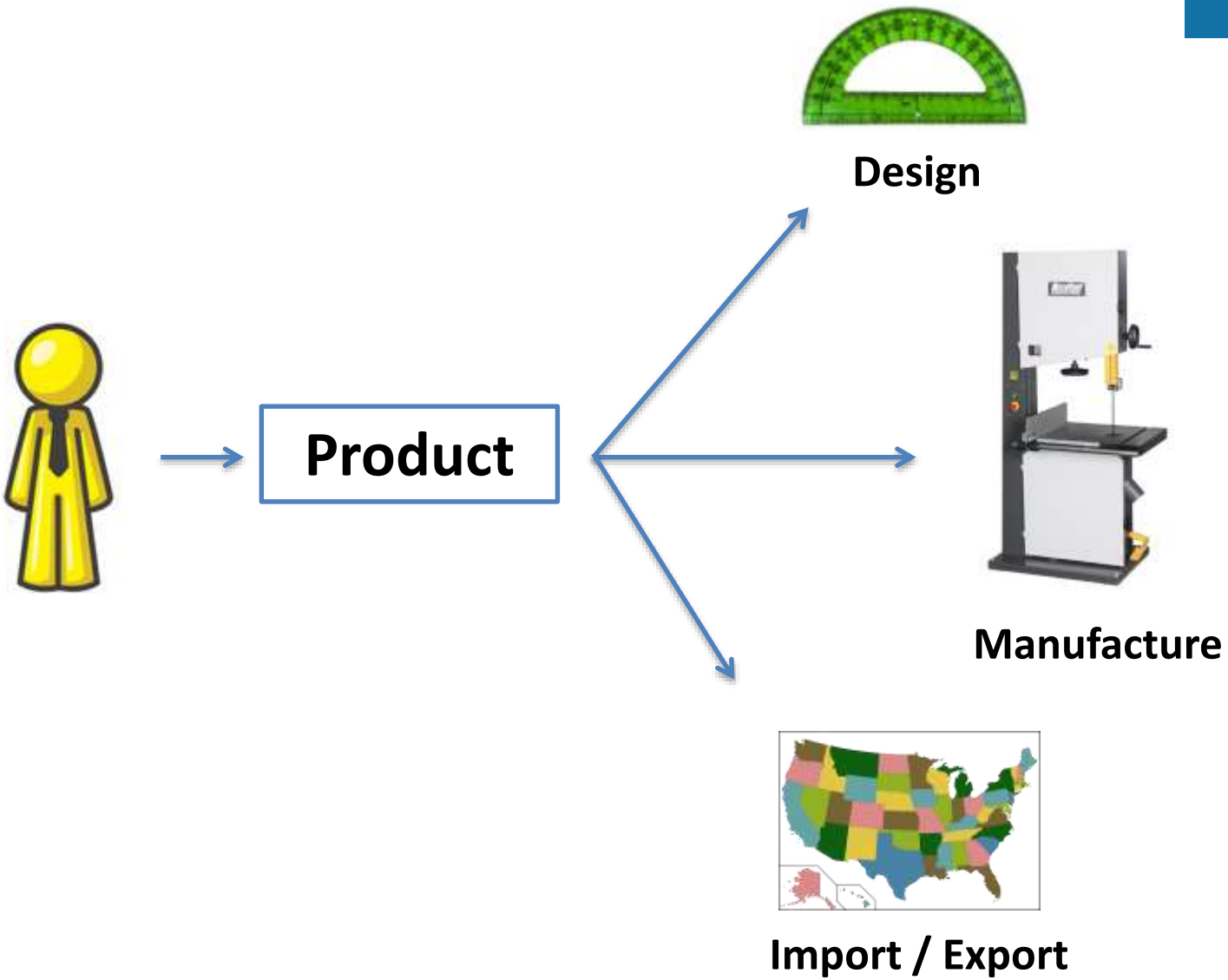
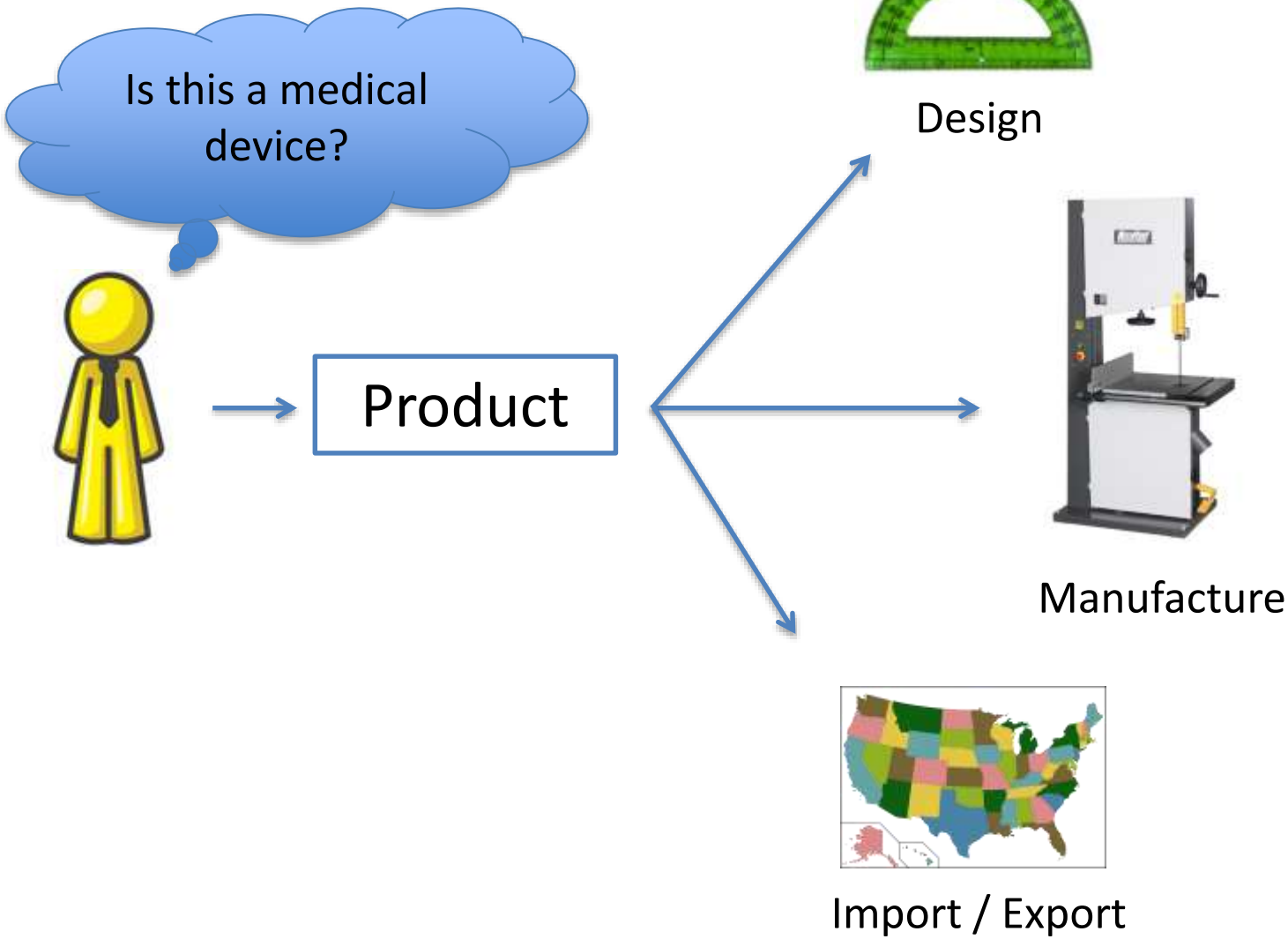
U.S. FOOD & DRUG ADMINISTRATION

CDRH Resources

FDA Small Business
Regulatory Education for Industry (REdI)
Silver Spring, MD
September 27, 2016

Diane Nell, Ph.D.
Premarket Programs Branch
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration


Design
Product
Manufacture
Import / Export


Is this a medical device?
Product
Design
Manufacture
Import / Export

Is this a medical device?

What are the steps to market?

Design

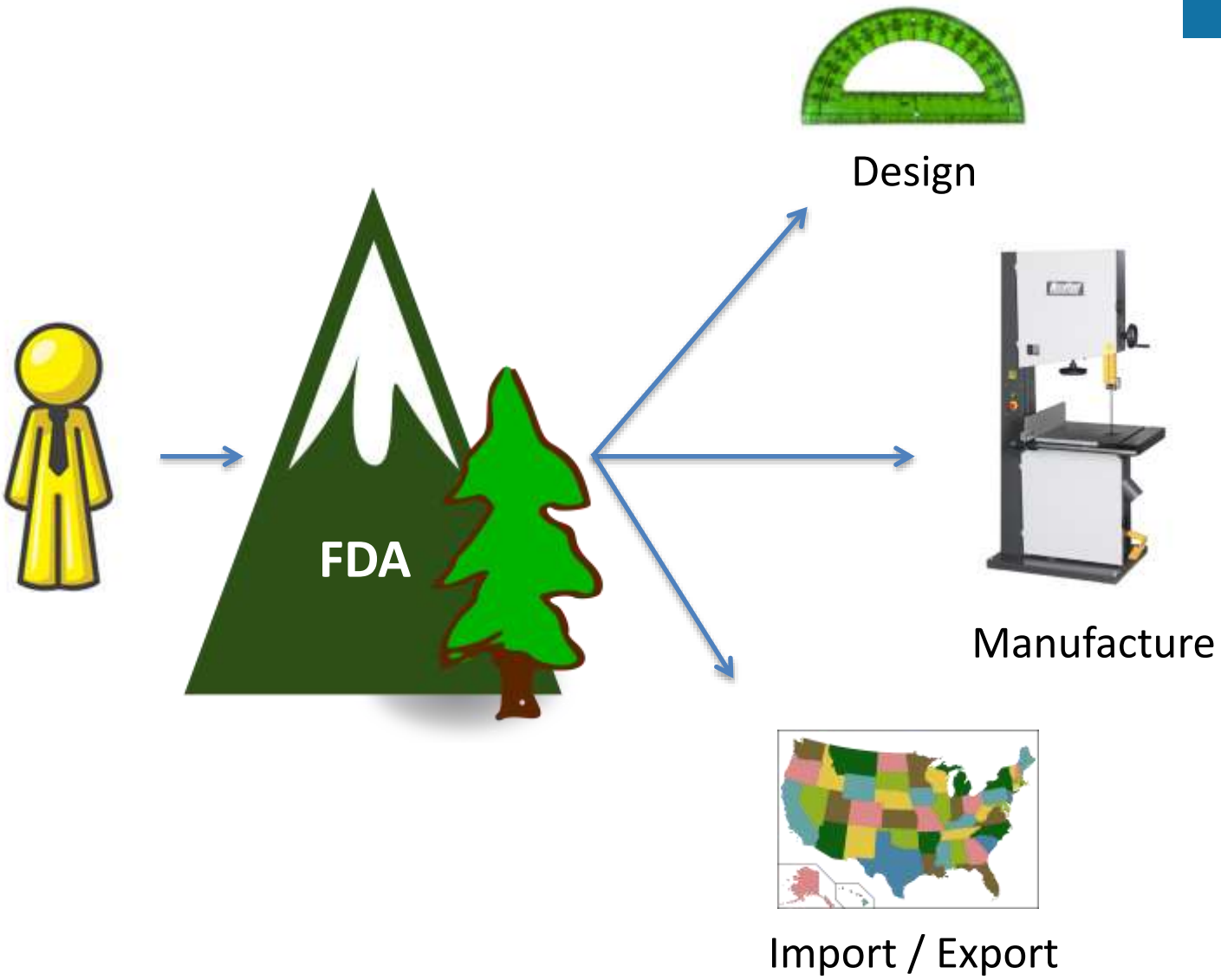
How long will it take?

How much will it cost?

Manufacture

What about after I market it?

Import / Export

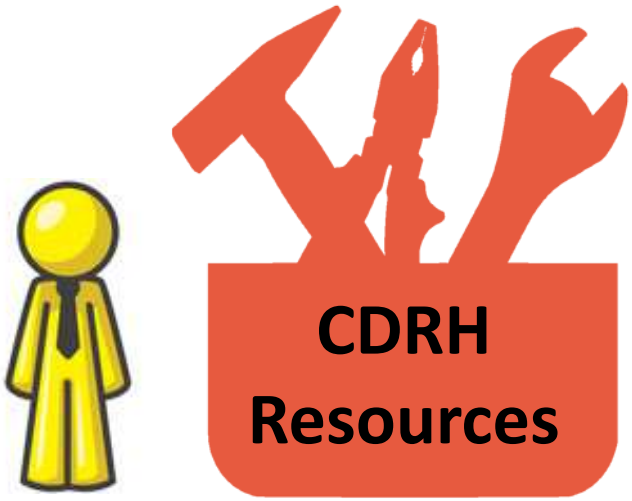

Design
FDA
Manufacture
Import / Export

www.fda.gov

An hour or two later ….

Common concerns we hear …

- **“Website is overwhelming”**
- **“I didn’t know where to start”**
- **“I got lost”**



Is this a medical device?

What are the steps to market?

How long will it take?

How much will it cost?

What about after I market it?

- "Hits" to webpages this year …
  - 8 million – Medical Devices main webpage
  - 3 million – Device Advice main webpage
  - 84 thousand – CDRH Learn webpage

Learning Objectives

- Understand primary resources:
  - **DICE**
  - **CDRH Learn**
  - **Device Advice**
- How to access available databases
- How to navigate website

Learning Objectives

- Understand primary resources:
  - **DICE**
  - **CDRH Learn**
  - **Device Advice**
- How to access available databases
- How to navigate website

DICE

- Division of Industry & Consumer Education
- Founded in 1976, *Medical Device Amendments* (formerly “DSMA” and “DSMICA”) as …

  "*an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices”*

- ~ 20 professionals

DICE Mission

- To **educate** our stakeholders with **understandable** and **accessible** science-based regulatory **information** about medical devices and radiation-emitting electronic products.

- To achieve our mission, we **stay current** on regulatory issues and new scientific advances, **anticipate** our stakeholder **needs** and ensure that the information we disseminate is accurate, timely, and appropriately targeted for each audience.

DICE: What We Do

- ~ 2,000 calls/mo (800) 638-2041 or (301) 796-7100
-

~ 1,000 emails/mo* (**DICE@fda.hhs.gov**)
- Deliver presentations - such as REdI!
- Develop web-based educational resources
  - CDRH Learn, Device Advice

* *Generally respond within 2 business days*

Learning Objectives

- Understand primary resources:
  - **DICE**
  - **CDRH Learn**
  - **Device Advice**
- How to access available databases
- How to navigate website

CDRH Learn

- Video-based presentations & slides
- > 100 training modules
- Topics …

★ **Start Here/The Basics!**
Registration and Listing

How to Study and Market Your Device - *(Updated module 9/7/16)*
510k, de novo, IDE, HUD/HDE, Pre-Submissions, Standards, Classification, Bioresearch Monitoring

Postmarket Activities - *(New modules 9/8/16)*
Quality System, Exporting, Device Recalls, MDR, Inspection - Global Harmonization

Unique Device Identification (UDI) System

Specialty Technical Topics - *(New module 9/14/16)*

Radiation-Emitting Products

In Vitro Diagnostics (IVD) - *(Updated module 8/18/16)*

Industry Basics Workshop Series

Learning Objectives

- Understand primary resources:
  - **DICE**
  - **CDRH Learn**
  - **Device Advice**
- How to access available databases
- How to navigate website

3

Device Advice

- Text-based information (webpages)
- ~ 280 webpages
- Covers:
  - Medical devices
  - Radiation-emitting electronic products
- Links to:
  - General information
  - Guidances and standards
  - Databases

Learning Objectives

- Understand primary resources:
  - **DICE**
  - **CDRH Learn**
  - **Device Advice**
- How to access available databases
- How to navigate website

10

Available Databases

U.S. Department of Health and Human Services

U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

Search FDA

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

Medical Devices

Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance > Medical Device Databases

Medical Device Databases

Medical Device Databases

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

Title	Description	Updated	More Information
AccessGUDID (Global Unique Device Identification Database)	This database contains key device identification information submitted to the FDA about medical devices that have Unique Device Identifiers (UDI).	Daily	More about GUDID
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
CDRH Export Certificate Validation (CECV)	This searchable database contains valid (not expired) export certificates submitted electronically via CECATS (CDRH Export Certification Application and Tracking System) and issued by the Center for Devices and Radiological Health. The results displayed include the facility name, certificate type, expiration date, certificate number, and the number of pages per certificate.	Weekly	
CDRH Inspections Database	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

10

Available Databases

- Product Classification
- Cleared/approved devices (510(k), PMA, HDE, etc.)
- MAUDE (Manufacturer & User Facility Device Experience; adverse event reports)
- Recalls
- Registration & Listing
- Guidances, standards, *more* ….

Learning Objectives

- Understand primary resources:
  - **DICE**
  - **CDRH Learn**
  - **Device Advice**
- How to access available databases
- How to navigate website

How to Navigate Website

Search window

Various boxes of information

Carousel of featured topics

(top portion of webpage)

(bottom portion of webpage)

- Follow Us on Twitter
- Subscribe to CDRH Mailing Lists
- About the Center for Devices and Radiological Health
- CDRH Management Directory by Organization
- Industry (Medical Devices)
- Health Care Providers (Medical Devices)
- Consumers (Medical Devices)

Program Areas

- Medical Device User Fee Amendments (MDUFA)
- In Vitro Diagnostics
- External Expertise and Partnerships (EEP)
- Standards (Medical Devices)
- CDRH Transparency
- Combination Products
- CDRH Mission, Vision and Shared Values

Industry Assistance

- Device Advice: Comprehensive Regulatory Assistance
- CDRH Learn
- Medical Device Webinars and Stakeholder Calls
- Premarket Requirements (How to Market Your Device)
- Postmarket Requirements (Devices)
- Importing and Exporting Devices
- Classify Your Medical Device
- Guidance Documents (Medical Devices and Radiation-Emitting Products)
- FDA eSubmitter

- FDA allows marketing of clot retrieval devices to reduce disability in stroke patients
- Recently-Approved Devices
- 510(k) Clearances
- PMA Approvals

Tools & Resources

- Device Registration and Listing
- Medical Device Databases
- FDA Recognized Consensus Standards Database
- CDRH Ombudsman
- Requesting Speakers from CDRH

Contact FDA

1-800-638-2041
301-796-7100
DICE@fda.hhs.gov

CDRH-Division of Industry and Consumer Education (DICE)
Office of Communication and Education
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

(bottom portion of webpage)

Contact FDA

1-800-638-2041
301-796-7100
DICE@fda.hhs.gov

CDRH-Division of Industry and Consumer Education (DICE)
Office of Communication and Education
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Amendments (MDUFA)

rtnerships (EEP)

es)

d Shared Values

nsive Regulatory Assistance

and Stakeholder Calls

(How to Market Your Device)

(Devices)

Devices

vice

- FDA allows marketing of clot retrieval devices to reduce disability in stroke patients
- Recently-Approved Devices
- 510(k) Clearances
- PMA Approvals

Tools & Resources

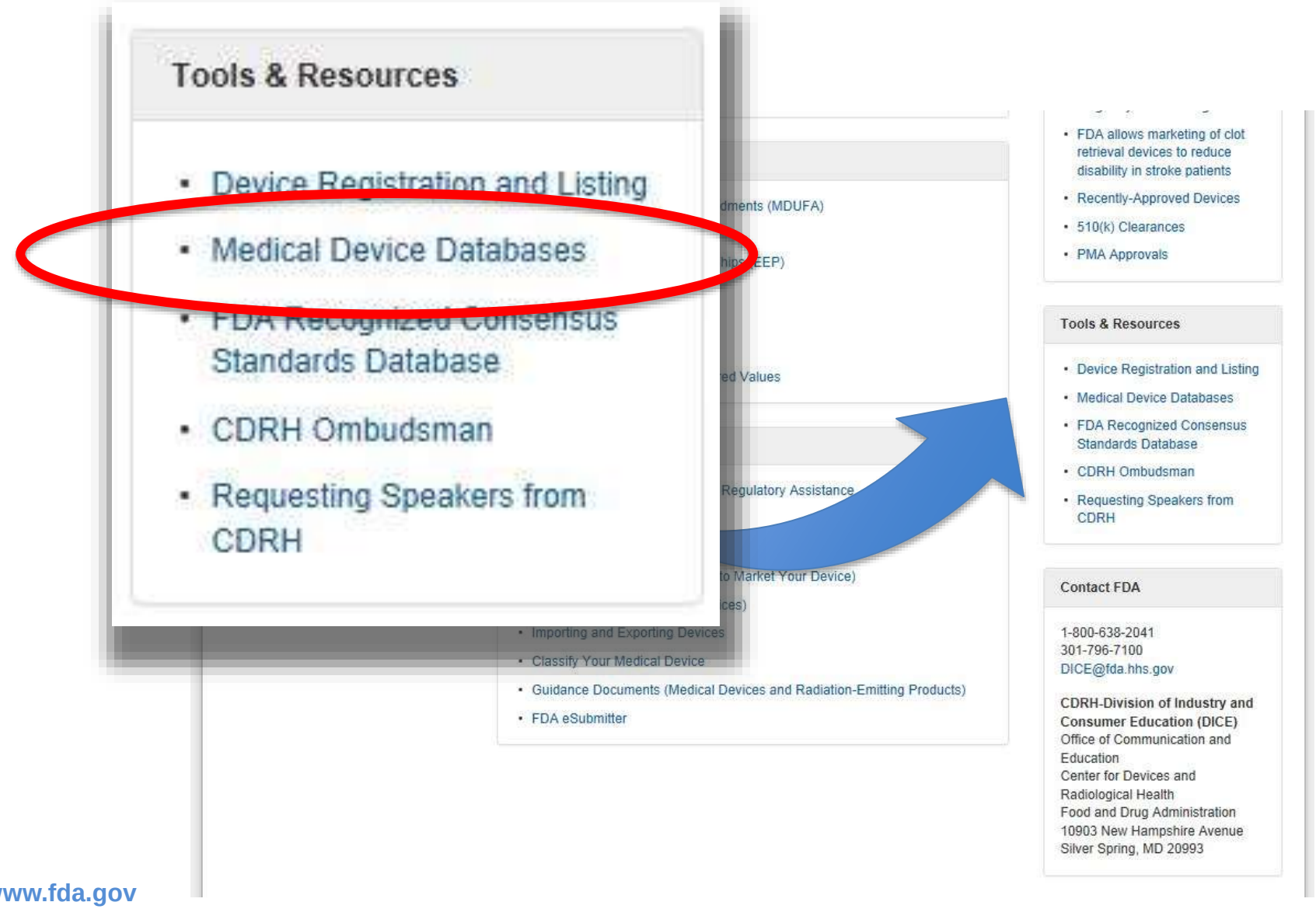
- Device Registration and Listing
- Medical Device Databases
- FDA Recognized Consensus Standards Database
- CDRH Ombudsman
- Requesting Speakers from CDRH

Contact FDA

1-800-638-2041
301-796-7100
DICE@fda.hhs.gov

CDRH-Division of Industry and Consumer Education (DICE)
Office of Communication and Education
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

(bottom portion of webpage)



(bottom portion of webpage)

Industry Assistance

- Device Advice: Comprehensive Regulatory Assistance
- CDRH Learn
- Medical Device Webinars and Stakeholder Calls
- Premarket Requirements (How to Market Your Device)
- Postmarket Requirements (Devices)
- Importing and Exporting Devices
- Classify Your Medical Device
- Guidance Documents (Medical Devices and Radiation-Emitting Products)
- FDA eSubmitter

Industry Assistance

- Device Advice: Comprehensive Regulatory Assistance
- CDRH Learn
- Medical Device Webinars and Stakeholder Calls
- Premarket Requirements (How to Market Your Device)
- Postmarket Requirements (Devices)
- Importing and Exporting Devices
- Classify Your Medical Device
- Guidance Documents (Medical Devices and Radiation-Emitting Products)
- FDA eSubmitter

- FDA allows marketing of clot retrieval devices to reduce disability in stroke patients
- Recently-Approved Devices
- 510(k) Clearances
- PMA Approvals

Tools & Resources

- Device Registration and Listing
- Medical Device Databases
- FDA Recognized Consensus Standards Database
- CDRH Ombudsman
- Requesting Speakers from CDRH

Contact FDA

1-800-638-2041
301-796-7100
DICE@fda.hhs.gov

CDRH-Division of Industry and Consumer Education (DICE)
Office of Communication and Education
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

(bottom portion of webpage)

Industry Assistance

- Device Advice: Comprehensive Regulatory Assistance
- CDRH Learn
- Medical Device Webinars and Stakeholder Calls
- Premarket Requirements (How to Market Your Device)
- Postmarket Requirements (Devices)
- Importing and Exporting Devices
- Classify Your Medical Device
- Guidance Documents (Medical Devices and Radiation-Emitting Products)
- FDA eSubmitter

- FDA allows marketing of clot retrieval devices to reduce disability in stroke patients
- Recently-Approved Devices
- 510(k) Clearances
- PMA Approvals

Industry Assistance

- Device Advice: Comprehensive Regulatory Assistance
- CDRH Learn
- Medical Device Webinars and Stakeholder Calls
- Premarket Requirements (How to Market Your Device)
- Postmarket Requirements (Devices)
- Importing and Exporting Devices
- Classify Your Medical Device
- Guidance Documents (Medical Devices and Radiation-Emitting Products)
- FDA eSubmitter

Tools & Resources

- Device Registration and Listing
- Medical Device Databases
- FDA Recognized Consensus Standards Database
- CDRH Ombudsman
- Requesting Speakers from CDRH

Contact FDA

1-800-638-2041
301-796-7100
DICE@fda.hhs.gov

CDRH-Division of Industry and Consumer Education (DICE)
Office of Communication and Education
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

U.S. Department of Health and Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | En Español

Search FDA

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

Medical Devices

Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance

- Device Advice: Comprehensive Regulatory Assistance
- Overview of Medical Device Regulation
- How to Study and Market Your Device
- Postmarket Requirements (Medical Devices)
- Quality and Compliance (Medical Devices)
- Human Factors (Medical Devices)
- Medical Device Databases
- Guidance Documents (Medical Devices and Radiation-Emitting Products)
- Standards (Medical Devices)
- Data Standards (Medical Devices)
- Reprocessing of Reusable Medical Devices: Information for Manufacturers
- Importing and Exporting Devices
- Unique Device Identification
- IVD Regulatory Assistance
- Contact Us -- Division of Industry and Consumer Education (DICE)

Device Advice: Comprehensive Regulatory Assistance

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

Welcome to Device Advice, the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) web page for comprehensive regulatory education. Device Advice is CDRH's premier text-based resource that explains many aspects of medical device laws, regulations, guidances, and policies, covering both premarket and postmarket topics.

Device Advice is intended to provide industry with information that is accurate, timely, comprehensive, and useful. For multi-media industry education, please also see CDRH Learn.

Additional Information

- Contact Us -- Division of Industry and Consumer Education (DICE)
- CDRH Management Directory by Organization
- CDRH Learn
- CDRH Referral List
- CDRH Outreach Emails
- Radiation-Emitting Products Resource Home Page
- Follow Us on Twitter

Spotlight

- CDRH Customer Service - Please take our survey
- eCopy Program for Medical Device Submissions
- National Medical Device Curriculum
- CDRH Transparency

Recalls & Alerts

- List of Device Recalls
- Recalls Database
- Safety Communications
- Medical Device Reporting (MDR)

Approvals & Clearances

- Recently-Approved Devices
- 510(k) Clearances
- PMA Approvals

Contact FDA

1-800-638-2041
301-796-7100
DICE@fda.hhs.gov

CDRH-Division of Industry and Consumer Education (DICE)
Office of Communication and Education
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

U.S. Department of Health and Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | En Español

Search FDA

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

Medical Devices

Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance

- Device Advice: Comprehensive Regulatory Assistance
- Overview of Medical Device Regulation
- How to Study and Market Your Device
- Postmarket Requirements (Medical Devices)
- Quality and Compliance (Medical Devices)
- Human Factors (Medical Devices)
- Medical Device Databases
- Guidance Documents (Medical Devices and Radiation-Emitting Products)
- Standards (Medical Devices)
- Data Standards (Medical Devices)
- Reprocessing of Reusable Medical Devices: Information for Manufacturers
- Importing and Exporting Devices
- Unique Device Identification
- IVD Regulatory Assistance
- Contact Us -- Division of Industry and Consumer Education (DICE)

Device Advice: Comprehensive Regulatory Assistance

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

Welcome to Device Advice, the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) web page for comprehensive regulatory education. Device Advice is CDRH's premier text-based resource that explains many aspects of medical device laws, regulations, guidances, and policies, covering both premarket and postmarket topics.

Device Advice is intended to provide industry with information that is accurate, timely, comprehensive, and useful. For multi-media industry education, please also see CDRH Learn.

Additional Information

- Contact Us -- Division of Industry and Consumer Education (DICE)
- CDRH Management Directory by Organization
- CDRH Learn
- CDRH Referral List
- CDRH Outreach Emails
- Radiation-Emitting Products Resource Home Page
- Follow Us on Twitter

Spotlight

- CDRH Customer Service - Please take our survey
- eCopy Program for Medical Device Submissions
- National Medical Device Curriculum
- CDRH Transparency

Recalls & Alerts

- List of Device Recalls
- Recalls Database
- Safety Communications
- Medical Device Reporting (MDR)

Approvals & Clearances

- Recently-Approved Devices
- 510(k) Clearances
- PMA Approvals

Contact FDA

1-800-638-2041
301-796-7100
DICE@fda.hhs.gov

CDRH-Division of Industry and Consumer Education (DICE)
Office of Communication and Education
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

U.S. Department of Health and Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | En Español

Search FDA

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

Medical Devices

Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance

- Device Advice: Comprehensive Regulatory Assistance
- Overview of Medical Device Regulation
- How to Study and Market Your Device
- Postmarket Requirements (Medical Devices)
- Quality and Compliance (Medical Devices)
- Human Factors (Medical Devices)
- Medical Device Databases
- Guidance Documents (Medical Devices and Radiation-Emitting Products)
- Standards (Medical Devices)
- Data Standards (Medical Devices)
- Reprocessing of Reusable Medical Devices: Information for Manufacturers
- Importing and Exporting Devices
- Unique Device Identification
- IVD Regulatory Assistance
- Contact Us -- Division of Industry and Consumer Education (DICE)

Device Advice: Comprehensive Regulatory Assistance

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

Welcome to Device Advice, the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) web page for comprehensive regulatory education. Device Advice is CDRH's premier text-based resource that explains many aspects of medical device laws, regulations, guidances, and policies, covering both premarket and postmarket topics.

Device Advice is intended to provide industry with information that is accurate, timely, comprehensive, and useful. For multi-media industry education, please also see CDRH Learn.

Additional Information

- Contact Us -- Division of Industry and Consumer Education (DICE)
- CDRH Management Directory by Organization
- CDRH Learn
- CDRH Referral List
- CDRH Outreach Emails
- Radiation-Emitting Products Resource Home Page
- Follow Us on Twitter

Spotlight

- CDRH Customer Service - Please take our survey
- eCopy Program for Medical Device Submissions
- National Medical Device Curriculum
- CDRH Transparency

Recalls & Alerts

- List of Device Recalls
- Recalls Database
- Safety Communications
- Medical Device Reporting (MDR)

Approvals & Clearances

- Recently-Approved Devices
- 510(k) Clearances
- PMA Approvals

Contact FDA

1-800-638-2041
301-796-7100
DICE@fda.hhs.gov

CDRH-Division of Industry and Consumer Education (DICE)
Office of Communication and Education
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

U.S. Department of Health and Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | En Español

Search FDA

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

Medical Devices

Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance

Device Advice: Comprehensive Regulatory Assistance

- Overview of Medical Device Regulation
- How to Study and Market Your Device
- Postmarket Requirements (Medical Devices)
- Quality and Compliance (Medical Devices)
- Human Factors (Medical Devices)
- Medical Device Databases
- Guidance Documents (Medical Devices and Radiation-Emitting Products)
- Standards (Medical Devices)
- Data Standards (Medical Devices)
- Reprocessing of Reusable Medical Devices: Information for Manufacturers
- Importing and Exporting Devices
- Unique Device Identification
- IVD Regulatory Assistance
- Contact Us -- Division of Industry and Consumer Education (DICE)

Device Advice: Comprehensive Regulatory Assistance

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

Welcome to Device Advice, the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) web page for comprehensive regulatory education. Device Advice is CDRH's premier text-based resource that explains many aspects of medical device laws, regulations, guidances, and policies, covering both premarket and postmarket topics.

Device Advice is intended to provide industry with information that is accurate, timely, comprehensive, and useful. For multi-media industry education, please also see CDRH Learn.

Additional Information

- Contact Us -- Division of Industry and Consumer Education (DICE)
- CDRH Management Directory by Organization
- CDRH Learn
- CDRH Referral List
- CDRH Outreach Emails
- Radiation-Emitting Products Resource Home Page
- Follow Us on Twitter

Spotlight

- CDRH Customer Service - Please take our survey
- eCopy Program for Medical Device Submissions
- National Medical Device Curriculum
- CDRH Transparency

Recalls & Alerts

- List of Device Recalls
- Recalls Database
- Safety Communications
- Medical Device Reporting (MDR)

Approvals & Clearances

- Recently-Approved Devices
- 510(k) Clearances
- PMA Approvals

Contact FDA

1-800-638-2041
301-796-7100
DICE@fda.hhs.gov

CDRH-Division of Industry and Consumer Education (DICE)
Office of Communication and Education
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

U.S. Department of Health and Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | En Español

Search FDA

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

Medical Devices

Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance

Device Advice: Comprehensive Regulatory Assistance

- Overview of Medical Device Regulation
- How to Study and Market Your Device
- Postmarket Requirements (Medical Devices)
- Quality and Compliance (Medical Devices)
- Human Factors (Medical Devices)
- Medical Device Databases
- Guidance Documents (Medical Devices and Radiation-Emitting Products)
- Standards (Medical Devices)
- Data Standards (Medical Devices)
- Reprocessing of Reusable Medical Devices: Information for Manufacturers
- Importing and Exporting Devices
- Unique Device Identification
- IVD Regulatory Assistance
- Contact Us -- Division of Industry and Consumer Education (DICE)

Device Advice: Comprehensive Regulatory Assistance

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

Welcome to Device Advice, the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) web page for comprehensive regulatory education. Device Advice is CDRH's premier text-based resource that explains many aspects of medical device laws, regulations, guidances, and policies, covering both premarket and postmarket topics.

Device Advice is intended to provide industry with information that is accurate, timely, comprehensive, and useful. For multi-media industry education, please also see CDRH Learn.

Additional Information

- Contact Us -- Division of Industry and Consumer Education (DICE)
- CDRH Management Directory by Organization
- CDRH Learn
- CDRH Referral List
- CDRH Outreach Emails
- Radiation-Emitting Products Resource Home Page
- Follow Us on Twitter

Spotlight

- CDRH Customer Service - Please take our survey
- Device Submissions
- National Medical Device Curriculum
- CDRH Transparency

Recalls & Alerts

- List of Device Recalls
- Recalls Database
- Safety Communications
- Medical Device Reporting (MDR)

Approvals & Clearances

- Recently-Approved Devices
- 510(k) Clearances
- PMA Approvals

Contact FDA

1-800-638-2041
301-796-7100
DICE@fda.hhs.gov

CDRH-Division of Industry and Consumer Education (DICE)
Office of Communication and Education
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

How to Navigate Website

Live Online Demo

What question do you want answered?

What question do you want answered?

View Votes | Edit | End Poll

What question do you want answered?

How do I classify my device?	0%	(0)
How can I get my device "approved"?	0%	(0)
Where can I find information about a device type and related standards and guidance documents?	0%	(0)
Where can I find information about a marketed device?	0%	(0)
What are the requirements for medical devices?	0%	(0)
Do I have to pay a fee? Is there a discount for small businesses?	0%	(0)
No Vote		

☑ Broadcast Results

How do I classify my device?

- 4 Review “medical device” definition
- 5 View “How to Study and Market Your Device” webpage → Step One: Classify Your Device
  - Product Classification Database

How do I classify my device?

How do I classify my device?

Product Classification

FDA Home › Medical Devices › Databases

This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA premarket review organizations, and other regulatory information.

Learn More...

Search Database

Help | Download Files

Device	ring	Product Code	
Review Panel		Regulation Number	
SubmissionType		Third Party Elligible	
Implanted Device		Device Class	
Life-Sustain/Support Device			

Go to Quick Search

Clear Form

Search

How do I classify my device?

Product Classification

FDA Home • Medical Devices • Databases

1 to 5 of 14 Results
ring

1 2 3 >

Results per Page 5

New Search

Export to Excel Help

Product Code	Device		Regulation Number	Device Class
OHX	Burr, Corneal, Ac-Powered, Rust Ring Removal	Powered Corneal Burr	886.4070	1
OHW	Burr, Corneal, Battery Powered, Rust Ring Removal	Powered Corneal Burr	886.4070	1
HFX	Clamp, Circumcision	Obstetric-Gynecologic Specialized Manual...	884.4530	2
NCE	Injector, Capsular Tension Ring	Intraocular Lens Guide	886.4300	1
KGW	Ring (Wound Protector), Drape Retention, Internal	Surgical Drape And Drape Accessories	878.4370	2

How do I classify my device?

Product Classification

FDA Home › Medical Devices › Databases

1 to 14 of 14 Results
ring

Results per Page 25

New Search

Export to Excel Help

Product Code	Device		Regulation Number	Device Class
OHX	Burr, Corneal, Ac-Powered, Rust Ring Removal	Powered Corneal Burr	886.4070	1
OHW	Burr, Corneal, Battery Powered, Rust Ring Removal	Powered Corneal Burr	886.4070	1
HFX	Clamp, Circumcision	Obstetric-Gynecologic Specialized Manual...	884.4530	2
NCE	Injector, Capsular Tension Ring	Intraocular Lens Guide	886.4300	1
KGW	Ring (Wound Protector), Drape Retention, Internal	Surgical Drape And Drape Accessories	878.4370	2
FNS	Ring Cutter	Ring Cutter	880.6200	1
KRH	Ring, Annuloplasty	Annuloplasty Ring	870.3800	2
FJX	Ring, Crimp	Blood Access Device And Accessories	876.5540	1
MRJ	Ring, Endocapsular			3
FJW	Ring, Joint	Blood Access Device And Accessories	876.5540	1
FHI	Ring, Laparotomy	Manual Gastroenterology-Urology Surgical...	876.4730	1
[illegible]	Ring, Ophthalmic (Fileringa)	Manual Ophthalmic Surgical Instrument	886.4350	1
KKO	Ring, Teething, Fluid-Filled	Teething Ring	872.5550	2
MEF	Ring, Teething, Non-Fluid Filled	Teething Ring	872.5550	1

Device	Ring, Teething, Fluid-Filled
Regulation Description	Teething ring.
Regulation Medical Specialty	Dental
Review Panel	Dental
Product Code	KKO
Premarket Review	Office of Device Evaluation (ODE) Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID) Dental Devices Branch (DEDB)
Submission Type	510(K) Exempt
Regulation Number	872.5550
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Note: Class II devices the Food and Drug Administration (FDA) has also published a list of Class II (special controls) devices subject to certain limitations, that are now exempt from the premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet a requirement of the Modernization Act.

Note: FDA intends to propose exempting these devices from premarket notification pursuant to the criteria at sections 510(l) and 510(m) of the FD&C Act, subject to limitations on exemption criteria found in .9 of the associated classification regulation. Until the publication of a final rule or order exempting these devices from 510(k), FDA does not intend to enforce compliance with 510(k) requirements for these devices. FDA does not expect manufacturers to submit 510(k)s for these devices during this time period.

Recognized Consensus Standard

- 4-212 ISO 7405 Second edition 2008-12-15
  Dentistry - Evaluation of biocompatibility of medical devices used in dentistry [Including: Amendment 1 (2013)]

Implanted Device?	No
Life-Sustain/Support Device?	No

Third Party Review

- Eligible for *Accredited Persons Expansion Pilot Program*

Accredited Persons

- Dekra Certification B.v.
- Regulatory Technology Services, Llc
- Third Party Review Group, Llc
- Tuv Sud America Inc.

This information is very important!

Device	Ring, Teething, Fluid-Filled
Regulation Description	Teething ring.
Regulation Medical Specialty	Dental
Review Panel	Dental
Product Code	KKO
Premarket Review	Office of Device Evaluation (ODE) Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID) Dental Devices Branch (DEDB)
Submission Type	510(K) Exempt
Regulation Number	872.5550
Device Class	2

New Search

Help | More About 21CFR

See Related Information

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2015]
[CITE: 21CFR872.5550]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 872 -- DENTAL DEVICES
Subpart F--Therapeutic Devices

Sec. 872.5550 Teething ring.

(a) *Identification.* A teething ring is a divice intended for use by infants for medical purposes to soothe gums during the teething process.
(b)(1) *Classification.* Class I if the teething ring does not contain a fluid, such as water. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.
(2) Class II if the teething ring contains a fluid, such as water.
[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63009, Dec. 7, 1994]

Total Product Life Cycle (TPLC) TPLC Product Code Report

GMP Exempt? No

Note: Class II devices the Food and Drug Administration (FDA) has also published a list of Class II (special controls) devices subject to certain limitations, that are now exempt from the premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet a requirement of the Modernization Act.

Note: FDA intends to propose exempting these devices from premarket notification pursuant to the criteria at sections 510(l) and 510(m) of the FD&C Act, subject to limitations on exemption criteria found in .9 of the associated classification regulation. Until the publication of a final rule or order exempting these devices from 510(k), FDA does not intend to enforce compliance with 510(k) requirements for these devices. FDA does not expect manufacturers to submit 510(k)s for these devices during this time period.

Recognized Consensus Standard

- 4-212 ISO 7405 Second edition 2008-12-15
  Dentistry - Evaluation of biocompatibility of medical devices used in dentistry [Including: Amendment 1 (2013)]

Implanted Device? No

Life-Sustain/Support Device? No

Third Party Review

- Eligible for *Accredited Persons Expansion Pilot Program*

Accredited Persons

- Dekra Certification B.v.
- Regulatory Technology Services, Llc
- Third Party Review Group, Llc
- Tuv Sud America Inc.

How do I classify my device?

4 • Review “medical device” definition

5 • View “How to Study and Market Your Device” webpage → Step One: Classify Your Device

– Product Classification Database

6 – Panel → view listing of devices in CFR

6

Medical Specialty		Regulation Citation (21CFR)
73	Anesthesiology	Part 868
74	Cardiovascular	Part 870
75	Chemistry	Part 862
76	Dental	Part 872
77	Ear, Nose, and Throat	Part 874
78	Gastroenterology and Urology	Part 876
79	General and Plastic Surgery	Part 878
80	General Hospital	Part 880
81	Hematology	Part 864
82	Immunology	Part 866
83	Microbiology	Part 866
84	Neurology	Part 882
85	Obstetrical and Gynecological	Part 884
86	Ophthalmic	Part 886
87	Orthopedic	Part 888
88	Pathology	Part 864
89	Physical Medicine	Part 890
90	Radiology	Part 892
91	Toxicology	Part 862

Medical Specialty		Regulation Citation (21CFR)
73	Anesthesiology	Part 868
74	Cardiovascular	Part 870
75	Chemistry	Part 862
76	Dental	Part 872
77	Ear, Nose, and Throat	Part 874
78	Gastroenterology and Urology	Part 876
79	General and Plastic Surgery	
80	General Hospital	
81	Hematology	
82	Immunology	
83	Microbiology	
84	Neurology	
85	Obstetrical and Gynecological	
86	Ophthalmic	
87	Orthopedic	
88	Pathology	
89	Physical Medicine	
90	Radiology	
91	Toxicology	

New Search

Help | More About 21CFR

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 872 DENTAL DEVICES

Subpart A--General Provisions

§ 872.1 - Scope.
§ 872.3 - Effective dates of requirement for premarket approval.
§ 872.9 - Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B--Diagnostic Devices

§ 872.1500 - Gingival fluid measurer.
§ 872.1720 - Pulp tester.
§ 872.1730 - Electrode gel for pulp testers.
§ 872.1740 - Caries detection device.
§ 872.1745 - Laser fluorescence caries detection device.
§ 872.1800 - Extraoral source x-ray system.
§ 872.1810 - Intraoral source x-ray system.
§ 872.1820 - Dental x-ray exposure alignment device.
§ 872.1830 - Cephalometer.
§ 872.1840 - Dental x-ray position indicating device.
§ 872.1850 - Lead-lined position indicator.

Subpart F--Therapeutic Devices

§ 872.5410 - Orthodontic appliance and accessories.
§ 872.5470 - Orthodontic plastic bracket.
§ 872.5500 - Extraoral orthodontic headgear.
§ 872.5525 - Preformed tooth positioner.
§ 872.5550 - Teething ring.
§ 872.5570 - Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.
§ 872.5580 - Oral rinse to reduce the adhesion of dental plaque.
§ 872.5560 - Electrical salivary stimulatory system.

How do I classify my device?

Product Classification

FDA Home › Medical Devices › Databases

This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA premarket review organizations, and other regulatory information.

Learn More...

Search Database Help Download Files

Device		Product Code	
Review Panel		Regulation Number	872.5550
SubmissionType		Third Party Elligible	
Implanted Device		Life-Sustain/Support Device	
Device Class			

Go to Quick Search Clear Form Search

How do I classify my device?

Product Classification

FDA Home › Medical Devices › Databases

1 to 2 of 2 Results
872.5550

Results per Page 5

New Search

Export to Excel Help

Product Code	Device		Regulation Number	Device Class
KKO	Ring, Teething, Fluid-Filled	Teething Ring	872.5550	2
MEF	Ring, Teething, Non-Fluid Filled	Teething Ring	872.5550	1

How do I classify my device?

7

- Request formal determination, including classification and requirements via 513(g) request
  - 2017 Fiscal Year Standard Fee: $3166
  - 2017 Fiscal Year Small Business Fee: $1583
- De Novo (no fee)

How can I get my device "approved"?

- "**Approved**" - PMA, HDE
- "**Cleared**" - 510(k) Premarket Notification
- "**Granted**" - *De Novo*
- Many class I devices are **Exempt** from premarket submission
  - subject to limitations in 21 CFR XXX.9 regulation

How can I get my device “approved”?

1. Review the “How to Study and Market Your Device” webpage
2. After you determine the proper classification, submit the appropriate pre-market application, if needed
3. Review the tabs and resources on each pre-market application webpage carefully
4. Register and List annually

Where can I find information about a device type and related standards and guidance documents?

- Product Classification Database
- Code of Federal Regulations, Title 21
- 8 Recognized Consensus Standards
- 9 Guidance Documents Database

Where can I find information about a marketed device?

10

- Databases:
  - PMA, 510(k), De Novo, etc.
  - Registration & Listing
  - MAUDE (adverse events)
  - Recalls
- AccessGUDID
- FOIA

What are the requirements for medical devices?

11

- Device Advice → Overview of Device Regulation

The basic regulatory requirements that manufacturers of medical devices distributed in the U.S. must comply with are:

- Establishment registration,
- Medical Device Listing,
- Premarket Notification 510(k), unless exempt, or Premarket Approval (PMA),
- Investigational Device Exemption (IDE) for clinical studies
- Quality System (QS) regulation,
- Labeling requirements, and
- Medical Device Reporting (MDR)

Do I have to pay a fee? Is there a discount for small businesses?

13

- "User Fees" webpage lists required fees, including:
  - R&L
  - Premarket submissions (some, not all)

14

- Small Business? → Reduced user fee, *if qualify*
  - To qualify, get SBD determination by FDA
  - SBD application is reviewed within 60 days
- "Small business" = gross receipts or sales ≤ **$100 million**

Summary of Resources

1. **CDRH Learn – Multi-Media Industry Education**
   - over 110 modules
   - videos, audio recordings, power point presentations, software-based "how to" modules
   - mobile-friendly: access CDRH Learn on your portable devices

   www.fda.gov/Training/CDRHLearn

2. **Device Advice – Text-Based Education**
   - over 250 web pages
   - comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/DeviceAdvice

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question about medical devices and rad health products
   - Email: **DICE@fda.hhs.gov**
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)

   www.fda.gov/DICE

Hyperlinks

1. Medical Device Homepage http://www.fda.gov/MedicalDevices/default.htm
2. CDRH Learn www.fda.gov/Training/CDRHLearn
3. Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm
4. Medical Device Definition http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm
5. How to Study and Market Your Device http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm
6. Device Classification Panels http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051530.htm
7. Formal Device Determination (513(g) Request) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM209851.pdf
8. Recognized Consensus Standards http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
9. Guidance Document Webpage http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

Hyperlinks

10. Medical Device Databases www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases
11. Device Advice: Overview of Device Regulation http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm
12. How to Get Records from CDRH http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHFOIAElectronicReadingRoom/default.htm
13. 2017 User Fees http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm514071.htm
14. "FY 2017 Medical Device User Fee Small Business Qualification and Certification" Guidance Document http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514085.pdf
15. FDA Forms http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm
16. CDRH Management Directory http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm127854.htm
17. Pre-Submission Program http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf
18. Subscribe to CDRH Mailing Lists http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm135906.htm

Summary of Resources

- ✓ CDRH Learn
- ✓ Device Advice
- ✓ DICE

Call to Action

- ✓ CDRH Learn
- ✓ Device Advice
- ✓ DICE

Slides

Video Presentation

Recorded Webinar

Call to Action

✓ CDRH Learn

✓ Device Advice

✓ DICE

View …

- Overview
- 510(k)
- R&L
- Quality System
- UDI
- Other specialty topics

Call to Action

✓ CDRH Learn

✓ Device Advice

- Browse webpages
- Bookmark key pages

✓ DICE

Call to Action

✓ CDRH Learn

✓ Device Advice

✓ DICE

Browse & bookmark …

- CDRH Learn
- Product Classification DB
- Databases (access to 510(k), MAUDE, Recalls …)
- Guidances
- Forms
- R&L
- Import / Export

Call to Action

- ✓ CDRH Learn
- ✓ Device Advice
- ✓ DICE

Please complete the session survey:

surveymonkey.com/r/DEV-D1S2

FDA U.S. FOOD & DRUG ADMINISTRATION