

# **Getting Started: CDRH Resources for You**

## **FDA Small Business Regulatory Education for Industry (REdI)**

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Center for Devices and Radiological Health  
U.S. Food and Drug Administration

help

# Learning Objectives

1. Introduce the Division and Industry and Consumer Education- referred to as D-I-C-E
2. Describe resources to assist you to navigate the Medical Device regulatory process
3. Identify CDRH Databases
4. Describe how to obtain updates from CDRH

# Who is DICE

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# DICE Basics

## **1. Independent group in CDRH**

- Congressional mandate to provide free information to medical device industry
- Not involved with developing policy or making regulatory decisions

## **2. Group of approximately 23 professionals**

- Diverse backgrounds: engineering, life science, clinical, legal
- Various experiences: FDA (regulatory); medical device industry; other government agencies; healthcare
- Experience in DICE: from 1 –30+ years



# DICE Vision

We ensure that stakeholders always have

- ✓ **accurate**
- ✓ **timely**
- ✓ **targeted**
- ✓ **useful**

educational information about medical devices and radiation-emitting electronic products.

# What Resources Are Available?

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# Resources

- Web based:
  - Device Advice
  - CDRH Learn
- Live Interactive Workshops:
  - Industry Basics
  - REdl
- Contact DICE for Device Regulatory Questions

## Medical Devices



### Conservation Strategies for Surgical Gowns and Masks

Mar 11 - The FDA is providing health care organizations and personnel with recommended conservation strategies for various supply levels of surgical masks and gowns during the COVID-19 outbreak.

Learn More



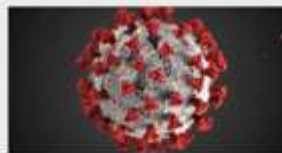
### N95 Respirators for Health Care Providers

Mar 3 - Authorization to allow health care personnel to use certain industrial respirators during the COVID-19 outbreak.



### SweynTooth Cybersecurity Vulnerabilities

Mar 3 - These vulnerabilities may introduce risks for certain medical devices that use Bluetooth Low Energy (BLE).



### Expediting Availability of COVID-19 Tests

Feb 29 - New policy for laboratories seeking to develop diagnostic tests for coronavirus (COVID-19).

#### NAVIGATE THE MEDICAL DEVICE SECTION

#### Device Advice

Information, education, and support for industry

#### Medical Device Safety

Safety Communications, Recalls, Letters to Health Care Providers, Reporting Adverse Events (MDR and MedSun)

#### Products and Medical Procedures

Approvals and clearances, information on medical devices by type

#### Digital Health

Cybersecurity, mobile medical applications, wireless medical devices, Software as Medical Device (SaMD)

**How to  
locate  
Device  
Advice-  
Medical Device  
Home page**

[www.fda.gov/medical-devices](https://www.fda.gov/medical-devices)

# Device Advice: Comprehensive Regulatory Assistance



## Device Advice: Comprehensive Regulatory Assistance

[Overview of Device Regulation](#)

[How to Study and Market Your Device](#)

[Postmarket Requirements \(Devices\)](#)

[Quality and Compliance \(Medical Devices\)](#)

[Human Factors and Medical Devices](#)

[Medical Device Databases](#)

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, encompassing the entire product life cycle.

### BRINGING A DEVICE TO MARKET

[Is it a Medical Device?](#)

[Medical Device User Fees](#)

[How to Study and Market Your Device](#)

[Device Registration and Listing](#)

# Device Advice

[www.fda.gov/deviceadvice](http://www.fda.gov/deviceadvice)

[Guidance Documents  
\(Medical Devices and  
Radiation-Emitting Products\)](#)

[Standards and Conformity  
Assessment Program](#)

[Data Standards and  
Terminology Standards for  
Information Submitted to  
CDRH](#)

[Reprocessing of Reusable  
Medical Devices: Information  
for Manufacturers](#)

[Importing and Exporting  
Medical Devices](#)

[Unique Device Identification  
System \(UDI System\)](#)

[IVD Regulatory Assistance](#)

[Contact Us -- Division of  
Industry and Consumer  
Education \(DICE\)](#)

## SEARCH MEDICAL DEVICE DATABASES

[All Medical Device Databases](#)

[Find FDA Guidance Documents](#)

[Find Medical Device Forms](#)

[Code of Federal Regulations \(CFR\)](#)

## RESOURCES



### Webinar

CDRH hosts webinars and calls to educate stakeholders on guidances and other topics related to the regulation of medical devices and radiation-emitting products. This web page contains information about such events, both past and upcoming.

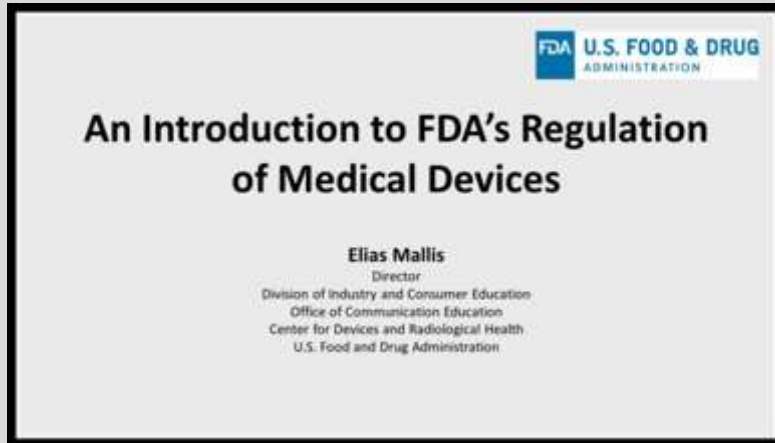


### CDRH Learn

CDRH Learn is our innovative educational tool, which consists of learning modules describing many aspects of medical device and radiation emitting product regulations, covering both premarket and postmarket topics.

# CDRH Learn

- Most are less than 20 minutes
- Mobile-friendly



[fda.yorkcast.com/webcast/Play/e0eec5f6ee3d4947a70fcedef32993f71d](https://fda.yorkcast.com/webcast/Play/e0eec5f6ee3d4947a70fcedef32993f71d)

**Start Here/The Basics!**

*MDUFA Small Business Program, Registration and Listing*



**How to Study and Market Your Device - (New module 12/4/19)**

*510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification*



**Postmarket Activities - (New module 1/13/20)**

*Quality System, Exporting, Device Recalls, MDR, Inspection - Global Harmonization*



**Unique Device Identification (UDI) System**



**Specialty Technical Topics - (New module 3/2/20)**



**Radiation-Emitting Products - (New module 1/13/20)**



**510(k) Third Party Review Program (for Third Party Review Organizations - (New modules 2/12/20)**



**Industry Basics Workshop Series - (New module - 11/29/19)**



# 8 Major Content Areas

## [Start Here/The Basics!](#)



### *MDUFA Small Business Program, Registration and Listing*

An Introduction to FDA's Regulation of Medical Devices

[Presentation](#) [Printable Slides](#) [Transcript](#)

How is CDRH Structured?

[Presentation](#) [Printable Slides](#) [Transcript](#)

Is My Product a Medical Device?

[Presentation](#) [Printable Slides](#) [Transcript](#)

Medical Device User Fee Amendments of 2017 (MDUFA IV): An Introduction

[Presentation](#) [Printable Slides](#) [Transcript](#)

# Content

# Getting Started: CDRH Learn Modules

- An Introduction to FDA's Regulation to Medical Devices
- Product Determination
- Device Classification
- Foundation modules for premarket programs
  - De Novo
  - 510(k)
  - PMA
  - HDE
  - IDE
- Overview of the Quality System



# Contact DICE for Device Questions



**1-800-638-2041**



**[DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)**

# What Additional Resources Are Available?

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# Industry Basics

- Two topics
- Dual Platform
  - Presentation
  - Live moderated Q+A session
    - Subject matter experts



**\*You can call or email your questions**

# Medical Device Databases



Title	Description	Updated	More Information
<a href="#">AccessGUDID (Global Unique Device Identification Database)</a>	This database contains key device identification information submitted to the FDA about medical devices that have Unique Device Identifiers (UDI).	Daily	<a href="#">More about GUDID</a>
<a href="#">Advisory Committee/Panel Meetings - CDRH</a>	This database contains historical information about CDRH Advisory Committees and Panel meetings through 2008, including summaries and transcripts.	No longer being updated	<a href="#">FDA Advisory Committees and Meeting Materials</a>
<a href="#">CDRH Export Certificate Validation (CECV)</a>	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	
<a href="#">CFR Title 21 - Food and Drugs</a>	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	<a href="#">More About 21CFR</a>
<a href="#">Clinical Laboratory Improvement Amendments (CLIA)</a>	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.	Weekly	<a href="#">Clinical Laboratory Improvement Amendments - Download Data</a>
<a href="#">CLIA Currently Waived Analytes</a>	This database contains the commercially marketed in vitro test systems categorized as CLIA waived by the FDA since January 31, 2000, and by the Centers for Disease Control and Prevention (CDC) prior to that date. CLIA waived test systems are waived from certain CLIA laboratory requirements (42 CFR Part 493).	Monthly	<a href="#">CLIA Waivers</a>

What  
Medical  
Devices  
Databases  
are  
Available?

# Frequently Used Medical Device Databases



Database	Information
<a href="#"><u>Product Classification</u></a>	Medical device names and associated information, a three letter device product code and a Class
Premarket Programs	Searchable for <a href="#"><u>Premarket Notifications (510(k)s)</u></a> , <a href="#"><u>Premarket Approvals (PMAs)</u></a> , <a href="#"><u>De Novo</u></a> , <a href="#"><u>Humanitarian Device Exemption (HDE)</u></a>
<a href="#"><u>Establishment Registration &amp; Listing</u></a>	Medical device manufacturers registered and medical devices listed with FDA

# Additional Medical Device Databases

- Recognized Consensus Standards
- Code of Federal Regulations (CFR)
- Manufacturer and User Facility Device Experience (MAUDE)
- Medical Device Reporting (MDR)
- Post-Approval Studies (PAS)

[www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases](https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases)

# How to Search FDA Databases?

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# Search

A510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act) that is not subject to premarket approval.

[Learn more...](#)

Search Database

 Help
  Download Files

510K Number

Type

Center

Applicant Name

Device Name

Cervical

Panel

Decision

Decision Date

to

Sort by

Decision Date (descending)

Product Code

ODP

Combined with previous

☐

Cleared/Approved in Vitro Products

☐

Redacted FOIA 510(k)

☒

Third Party Reviewed

☐

Clinical Trials

☐

[Quick Search](#)

[Clear Form](#)

Search

# Search Results

1 to 10 of 147 Results  
 Product Code: o/p Device Name: Cervical  
 Decision Date To: 07/22/2020

1 2 3 4 5 6 7 8 9 10 > Results per Page 10

[Export to Excel](#) | [Download Files](#) | [More About 510\(k\)](#)

Device Name	Applicant	510(k) Number	Decision Date
<a href="#">Eit Cellular Titanium Cervical Cage, Eit Cellular Titanium Alif Cage, Eit Cellular Titanium Tlif Cage, Eit Cellular Titanium Llif Cage, Eit Cellular Titanium T/Plif Cage</a>	EIT Emerging Implant Technologies GmbH	<a href="#">K201605</a>	07/15/2020
<a href="#">Rigel 3dr Anterior Cervical Interbody Fusion System</a>	MiRus, LLC	<a href="#">K200685</a>	06/11/2020
<a href="#">Icotec Cervical Cage</a>	Icotec Ag	<a href="#">K192897</a>	03/20/2020
<a href="#">Omnia Medical Tibrid Cervical Cage, Omnia Medical Tibrid Lateral Cage, Omnia Medical Tibrid Alif Cage, Omnia Medical Tibrid Plif Cage, Omnia Medical Tibrid Tlif Cage</a>	Omnia Medical, LLC	<a href="#">K190363</a>	02/21/2020
<a href="#">Genesys Spine 3dp Cervical Interbody System</a>	Genesys Spine	<a href="#">K191489</a>	01/08/2020
<a href="#">Suremax Family Of Cervical Spacers</a>	Additive Implants, Inc	<a href="#">K193359</a>	01/03/2020
<a href="#">Adi Cervical Interbody Fusion Device</a>	Additive Device, Inc. (ADI) D/B/A Restor3d	<a href="#">K191812</a>	10/24/2019
<a href="#">Matrix Ha Peek Cervical Implant System</a>	Sapphire Medical Group	<a href="#">K192316</a>	10/17/2019
<a href="#">Cornice Cervical Spacer System</a>	Legend Spine Technologies	<a href="#">K192208</a>	10/09/2019
<a href="#">Hedron Cervical Spacers</a>	Globus Medical Inc.	<a href="#">K191243</a>	09/17/2019

# Product Information

[New Search](#)
[Back To Search Results](#)

Device Classification Name	<a href="#">Intervertebral Fusion Device With Bone Graft, Cervical</a>
510(k) Number	K121741
FOIA Releasable 510(k)	K121741
Device Name	4-WEB CERVICAL STS (SPINAL TRUSS SYSTEM)
Applicant	4-WEB, INC. 13540 GUILD AVE. Apple Valley, MN 55124
Applicant Contact	Rich Jansen, Pharm, D.
Correspondent	4-WEB, INC. 13540 GUILD AVE. Apple Valley, MN 55124
Correspondent Contact	Rich Jansen, Pharm, D.
Regulation Number	888.3080
Classification Product Code	ODP
Date Received	06/13/2012
Decision Date	10/18/2012
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Orthopedic
510(k) Review Panel	Orthopedic
Summary	<a href="#">Summary</a>
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

# Quick Search

## 510(K) Premarket Notification

[FDA Home](#) [Medical Devices](#) [Databases](#)

A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act) that is not subject to premarket approval.

[Learn more...](#)

[Advanced Search](#)

### Tips for Searching:

- Conduct multiple searches using a variety of related terms
- Narrow search with multiple criteria
- Spelling and plural and singular matter

# Example

Search	Results
ODP	342
ODP, Cervical	147
ODP, Cervical, System	87
ODP, Cervical, System <sup>s</sup>	0
ODP, Cervical System, FOIA	1












# How To Keep Track Of What Is Happening at CDRH

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# Medical Device Subscriptions

<https://updates.fda.gov/subscriptionmanagement>

- ☐ ☐ Medical Devices
  - ☐ CDRH Industry 
  - ☐ CDRH New 
  - ☐ CDRH Science 
  - ☐ Consumer Information for Medical Devices 
  - ☐ Digital Health 
  - ☐ GUDID System Status 
  - ☐ InVitro Diagnostics 
  - ☐ Mammography 
  - ☐ Medical Device Safety and Recalls 
  - ☐ Medical Device Single Audit Program (MDSAP) 
  - ☐ MedSun 
  - ☐ MedWatch Safety Alerts: FDA Safety Information 
  - ☐ Private Payer Communication 
  - ☐ Recent Device Approvals 
  - ☐ Unique Device Identification 

# Industry Education: Three Resources for You

1. **CDRH Learn: Multi-Media Industry Education**
  - over 150 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-and-continuing-education/cdrh-learn](http://www.fda.gov/training-and-continuing-education/cdrh-learn)
2. **Device Advice: Text-Based Education**
  - over 300 pages
  - comprehensive written regulatory information on premarket and postmarket topics

[www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance](http://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance)
3. **Division of Industry and Consumer Education (DICE)**
  - Contact DICE if you have a question
  - Email: [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)
  - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
  - Web: [www.fda.gov/DICE](http://www.fda.gov/DICE)

# Knowledge Check

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# Knowledge Check

What CDRH resource contains over 300 pages of text based regulatory information to assist you?

1. Device Advice
2. CDRH Learn
3. Both

# Knowledge Check

What resource contains multimedia modules on regulatory topics?

1. Device Advice
2. CDRH Learn
3. Movie Theater

# Knowledge Check

**Who can you contact to get information on the regulatory process to market a medical device?**

1. Health and Human Services (HHS)
2. National Institutes of Health (NIH)
3. Division of Industry and Consumer Education (DICE)

# Summary



- **CDRH educational resources**
  - Device Advice
  - CDRH Learn
- **Live Conferences**
  - Industry Basics
  - REdl
- **Medical Device Databases**

# Summary

- **“Be in the Know”**
  - CDRH Subscriptions
- **Contact DICE**
  - Phone: 1-800-638-2041
  - Email: [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)



# Questions



