Getting Started:
CDRH Resources for You

FDA Small Business Regulatory Education for Industry (REdI)

Silver Spring, MD

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Division of Industry and Consumer Education

Office of Communication and Education

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

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

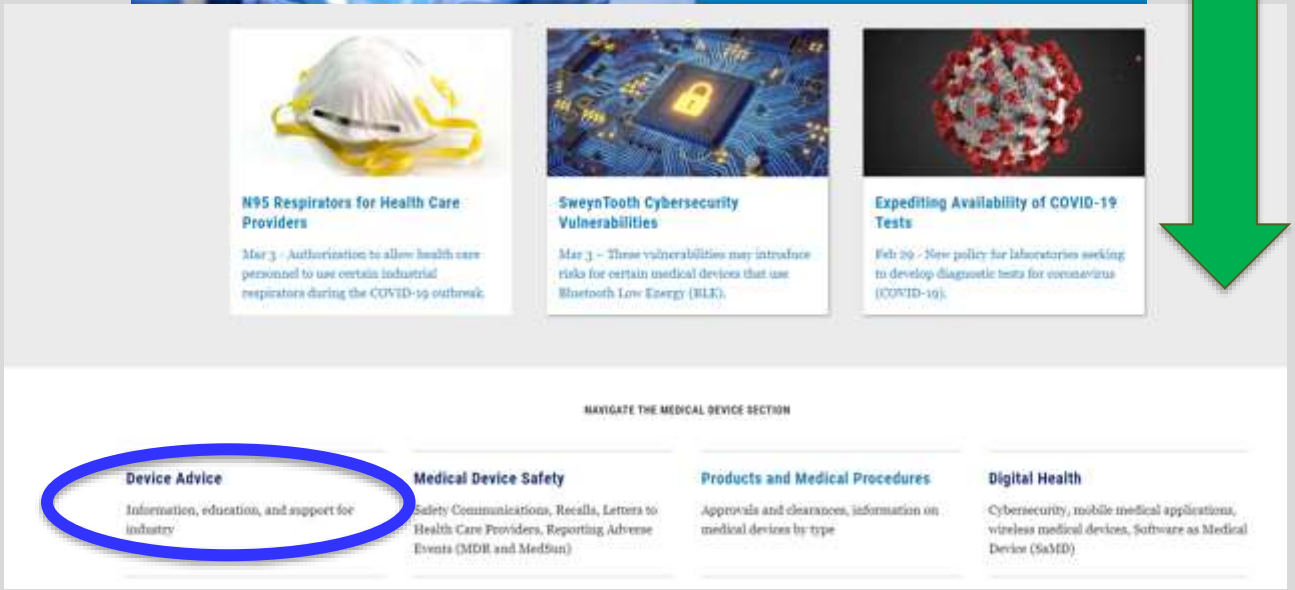
- ✓ **accurate**
- ✓ **timely**
- ✓ **targeted**
- ✓ **useful**

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

What Resources Are Available?

Resources

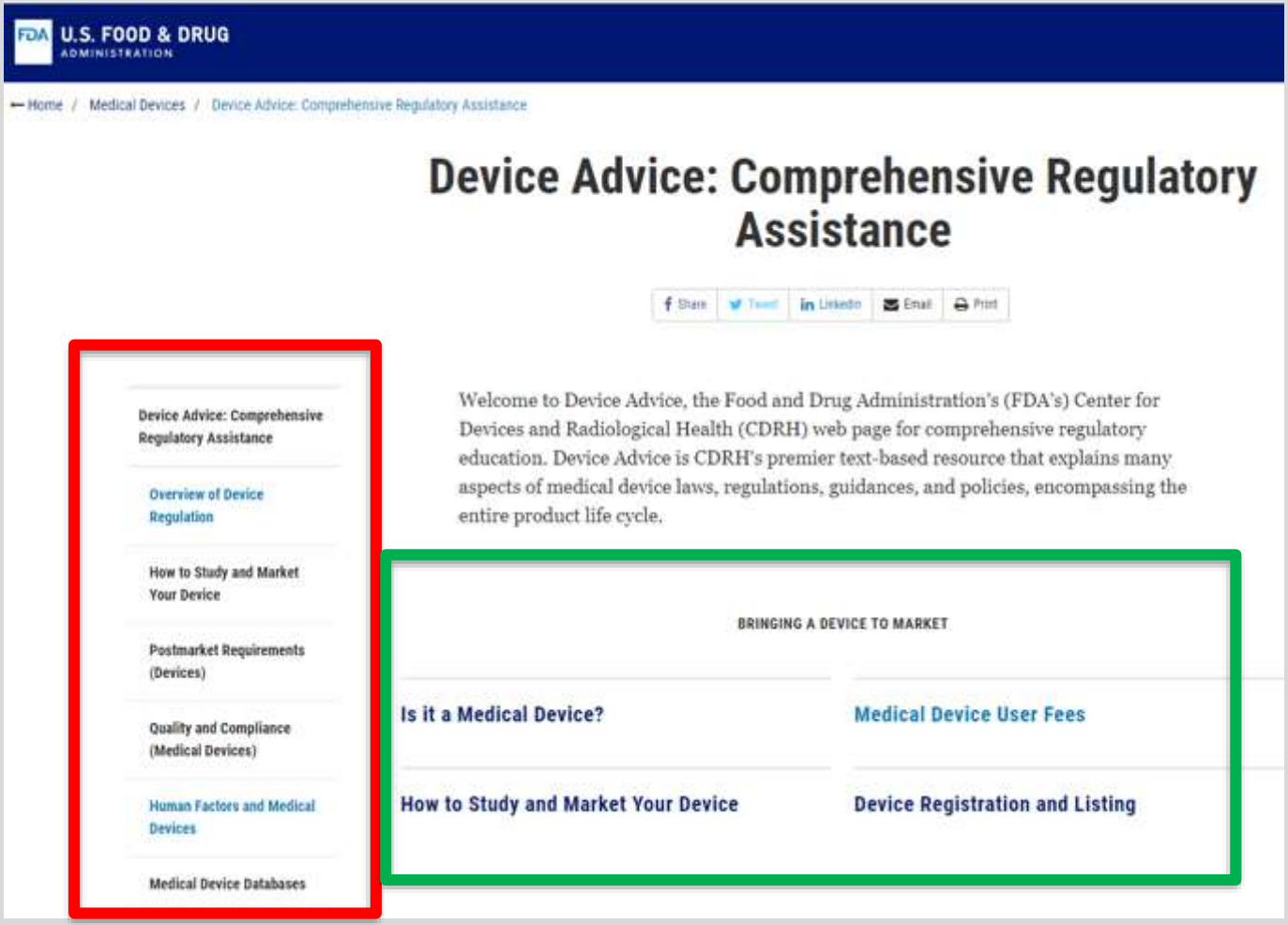
- Web based:
  - Device Advice
  - CDRH Learn
- Live Interactive Workshops:
  - Industry Basics
  - REdI
- Contact DICE for Device Regulatory Questions



How to locate Device Advice-

Medial Device Home page

www.fda.gov/medical-devices



Device Advice

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.

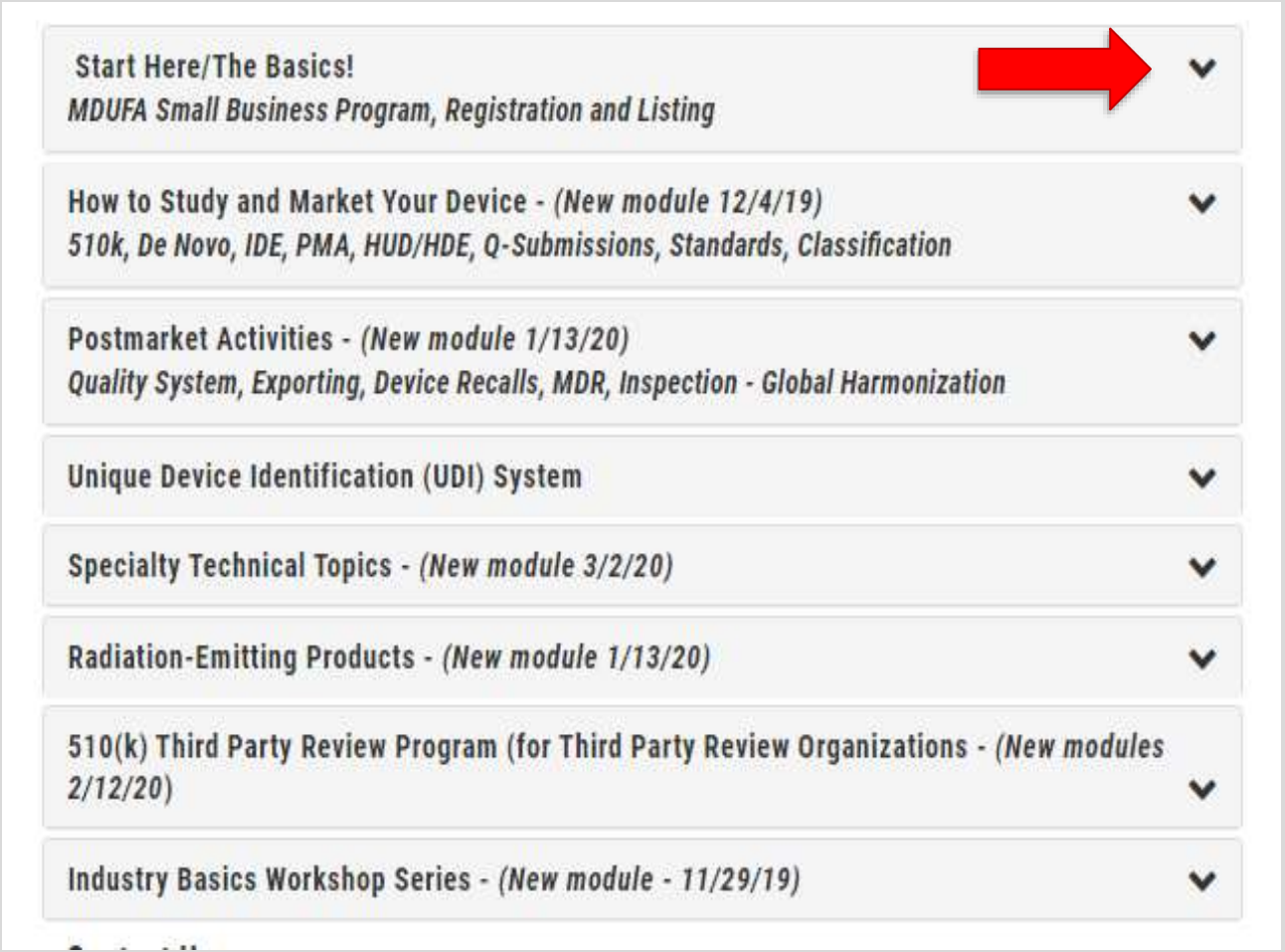
CDRH Learn

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.

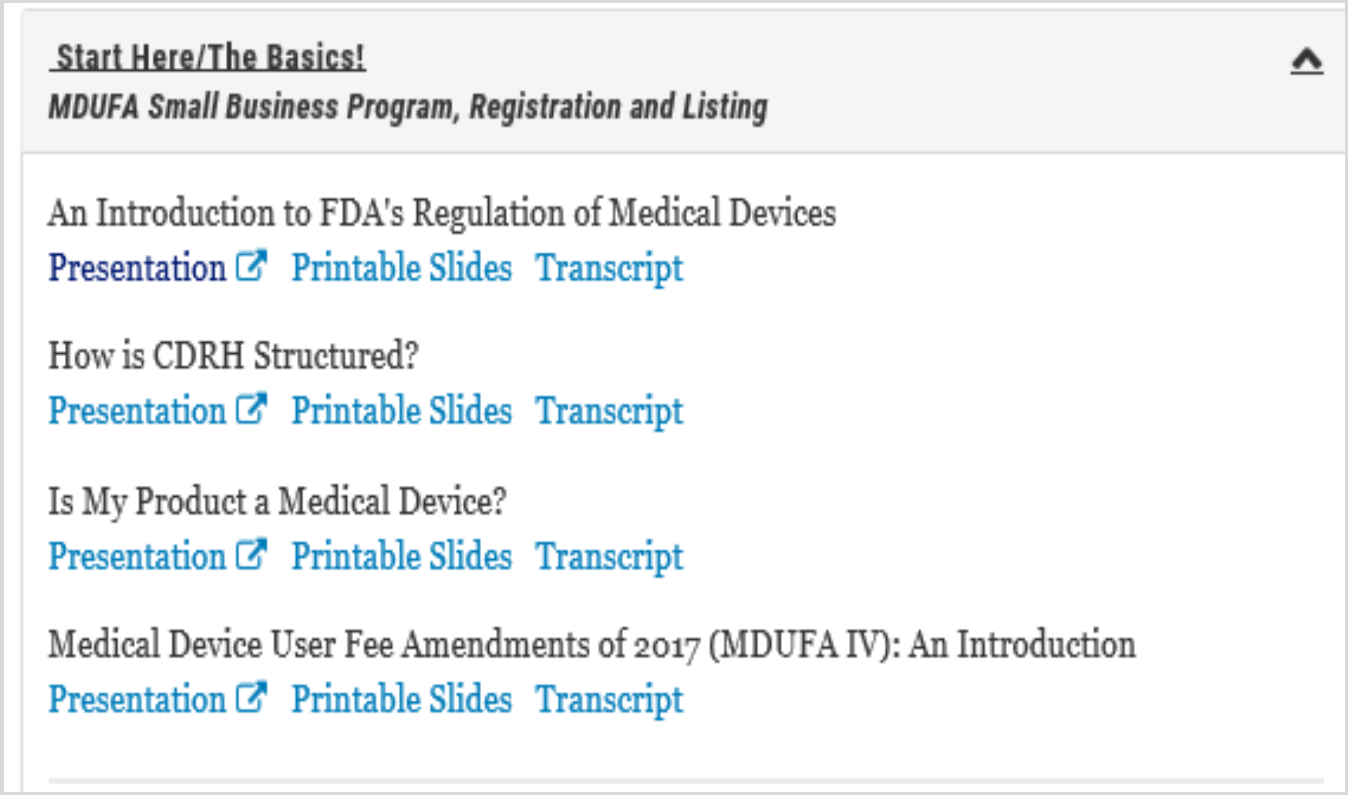
CDRH Learn

- Most are less than 20 minutes
- Mobile-friendly

fda.yorkcast.com/webcast/Play/e0eec5f6ee3d4947a70fcedef32993f71d



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

What Additional Resources Are Available?

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

Share | Tweet | Linkedin | 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	
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.	Weekly	Clinical Laboratory Improvement Amendments - Download Data
CLIA Currently Waived Analytes	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	CLIA Waivers

What Medical Devices Databases are Available?

Frequently Used Medical Device Databases

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

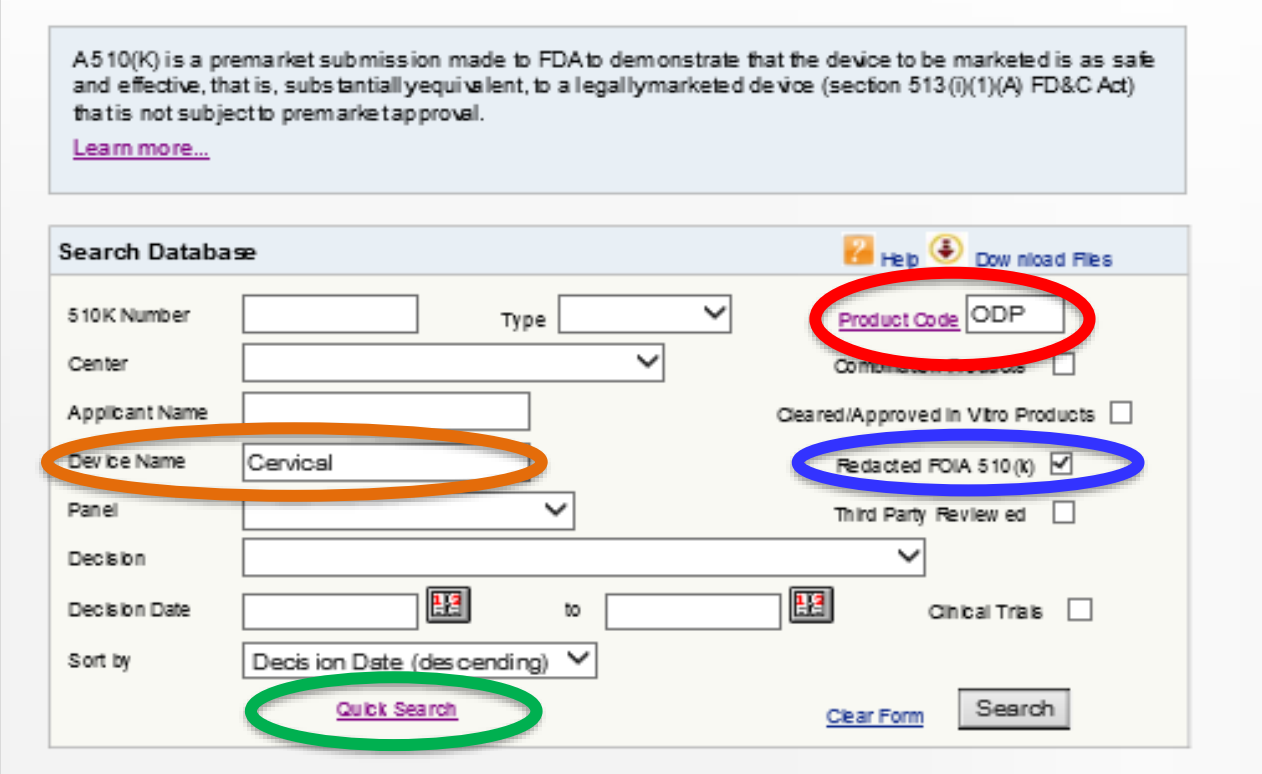
Additional Medical Device Databases

- 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

How to Search FDA Databases?

Search


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...
Search Database
Help
Download Files
510K Number
Type
Product Code
ODP
Center
Applicant Name
Cleared/Approved In Vitro Products
Device Name
Cervical
Redacted FOIA 510(k)
Panel
Third Party Reviewed
Decision
Decision Date
to
Clinical Trials
Sort by
Decision Date (descending)
Quick Search
Clear Form
Search

Search Results

1 to 10 of 147 Results
ProductCode: odp Device Name: Cervical
Decision Date To: 07/22/2020

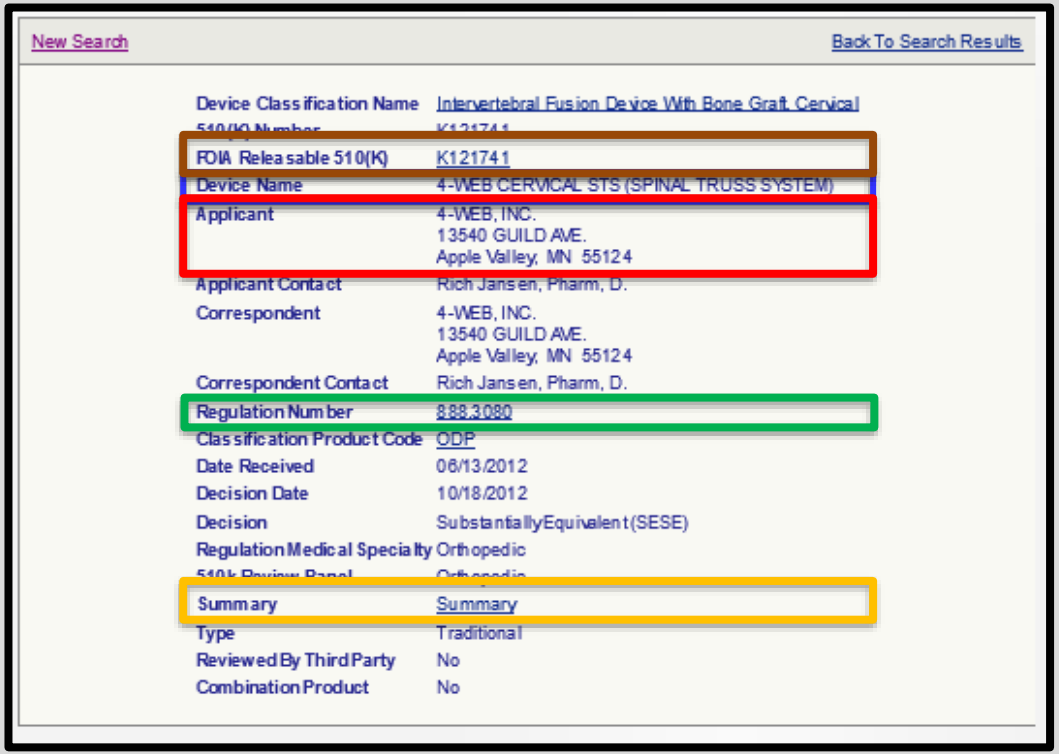
1 2 3 4 5 6 7 8 9 10 >

Results per Page 10

Export to Excel | Download Files | More About 510(k)

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

Product Information



New Search | Back To Search Results

Device Classification Name	Intervertebral Fusion Device With Bone Graft, Cervical
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	SubstantiallyEquivalent(SESE)
Regulation Medical Specialty	Orthopedic
510k Review Panel	Orthopedic
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Quick 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, Systems	0
ODP, Cervical System, FOIA	1

How To Keep Track Of What Is Happening at CDRH

Medical Device Subscriptions

https://updates.fda.gov/subscriptionmanagement

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

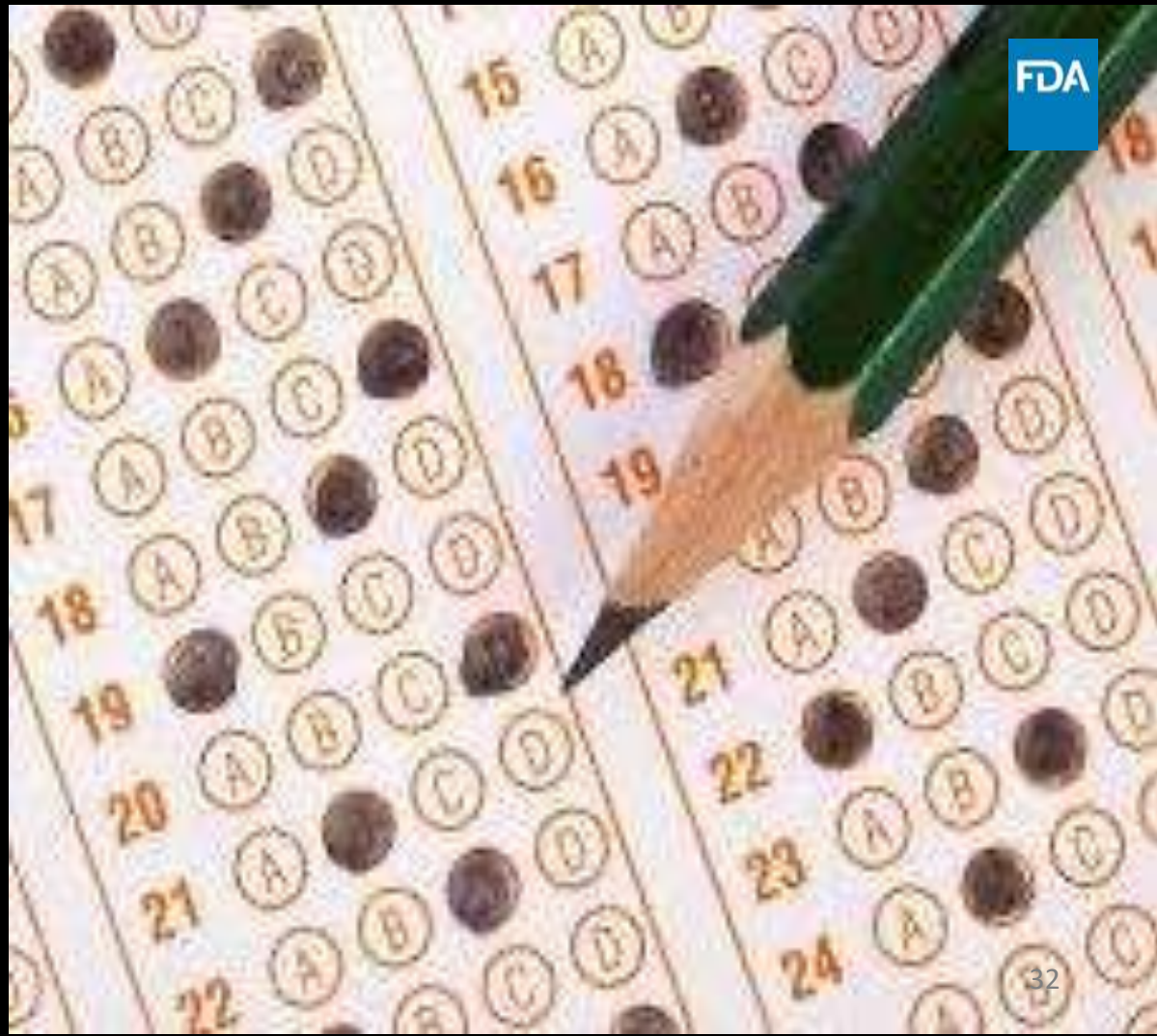
   www.fda.gov/training-and-continuing-education/cdrh-learn

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

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - 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)
   - Web: www.fda.gov/DICE

Knowledge Check



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
  - REdI
- **Medical Device Databases**

Summary

- **“Be in the Know”**
  - CDRH Subscriptions
- **Contact DICE**

  Phone: 1-800-638-2041

  Email: DICE@fda.hhs.gov

Questions


FDA
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ADMINISTRATION