ORA/CDRH Resources Available to Industry

Ruth Bediakoh
Consumer Safety Officer,
Division of Industry and Consumer Education
Center for Devices and Radiological Health (CDRH)

David C. Sullivan, Ph.D., CQA
Lieutenant Commander, U.S. Public Health Service
Consumer Safety Officer, FDA/OMDRHO

Justine Corson
Medical Device Specialist
Consumer Safety Officer, FDA/OMDRHO

Learning Objectives

- Review background information about medical device resources for industry
- Describe the types of resources available
- Discuss how to locate resources
- Identify who to contact for regulatory education and assistance

Background Information for Medical Device Resources

- Mandated in 1976 to provide technical and regulatory assistance to small manufacturers
- Developed the role of the Division of Industry and Consumer Education (DICE)
  - Develops educational resources constantly
  - Ensures information is accurate, timely and meets audience needs

DICE Mission Statement

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

DICE Activities

- Respond to industry and consumer inquiries
  - **Written** and **Oral inquiries**
  - Develop and update educational resources
    - Device Advice and CDRH Learn
- Co-sponsors Regulatory Education for Industry (REdI) Conference
- Conduct Industry Basics webinars

DICE Educational Resources

- **Device Advice**
  - Text-Based Education
  - Over 300 pages of premarket/postmarket regulatory information
  - **www.fda.gov/DeviceAdvice**

DICE Educational Topics

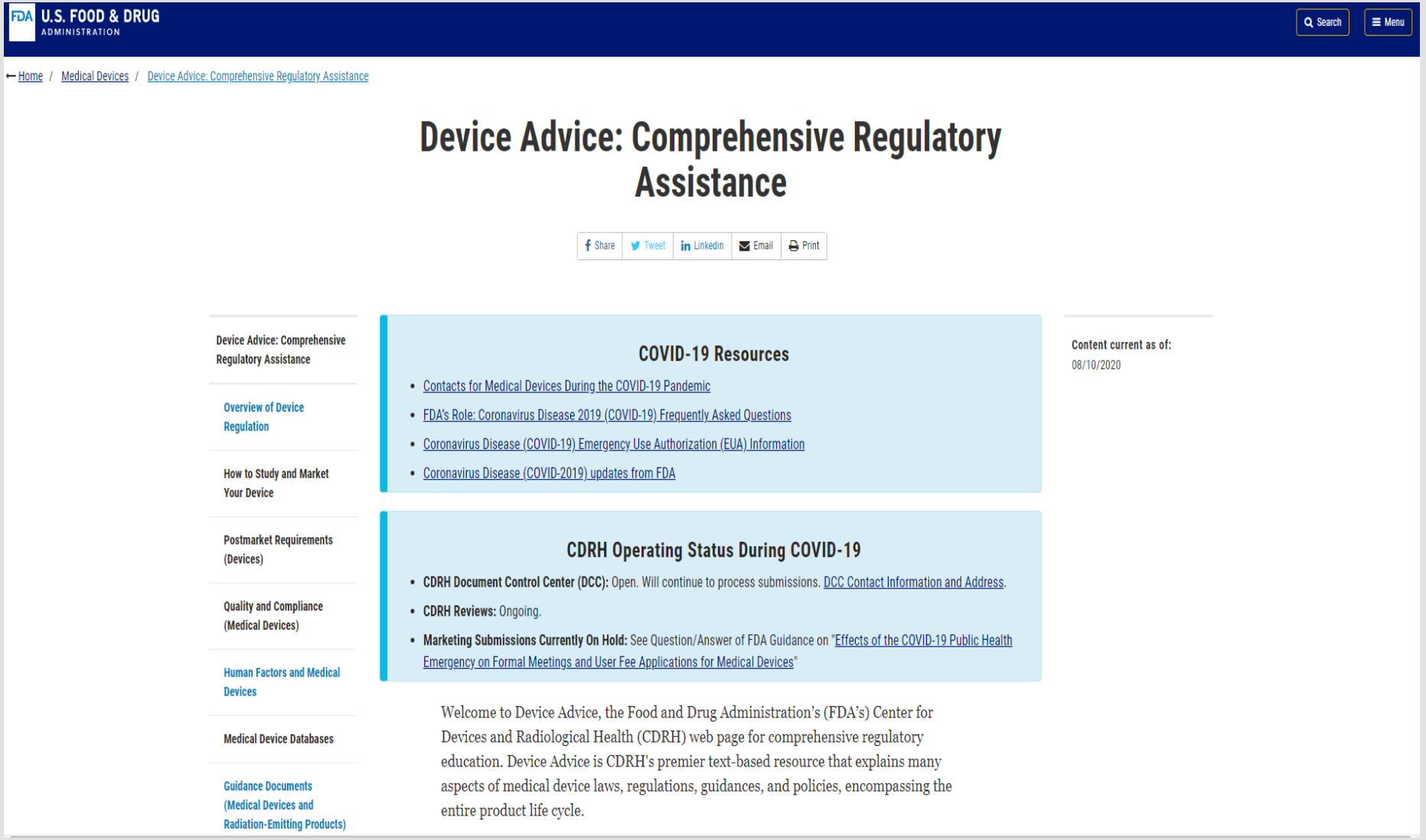
Premarket

- How do I market a device?
- Device classification
- Premarket applications
- FDA laws, regulations, guidance, and policies

Postmarket

- Quality System
- Medical device reporting
- Recalls and corrections
- Imports/Exports
- Registration and listing

Device Advice – www.fda.gov/DeviceAdvice



U.S. FOOD & DRUG ADMINISTRATION

Search | Menu

Home / Medical Devices / Device Advice: Comprehensive Regulatory Assistance

Device Advice: Comprehensive Regulatory Assistance

Share | Tweet | LinkedIn | Email | Print

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
- Guidance Documents (Medical Devices and Radiation-Emitting Products)

COVID-19 Resources

- Contacts for Medical Devices During the COVID-19 Pandemic
- FDA's Role: Coronavirus Disease 2019 (COVID-19) Frequently Asked Questions
- Coronavirus Disease (COVID-19) Emergency Use Authorization (EUA) Information
- Coronavirus Disease (COVID-2019) updates from FDA

CDRH Operating Status During COVID-19

- **CDRH Document Control Center (DCC):** Open. Will continue to process submissions. DCC Contact Information and Address.
- **CDRH Reviews:** Ongoing.
- **Marketing Submissions Currently On Hold:** See Question/Answer of FDA Guidance on "Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices"

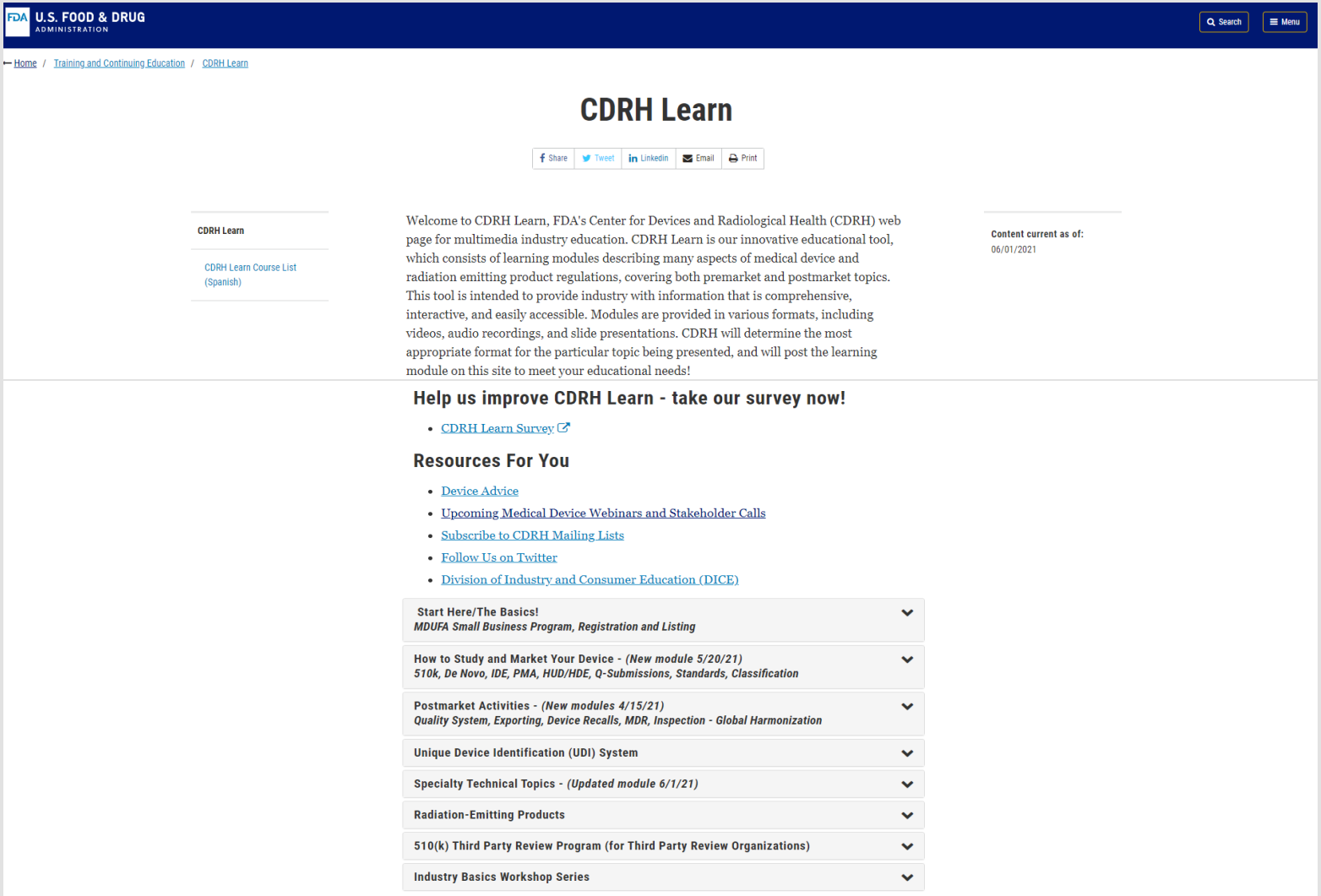
Welcome to Device Advice, the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) web page for comprehensive regulatory education. Device Advice is CDRH's premier text-based resource that explains many aspects of medical device laws, regulations, guidances, and policies,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

Content current as of:
08/10/2020

DICE Educational Resources

- **CDRH Learn**
  - Multi-Media Industry Education
  - 260 modules
  - Videos, audio recordings, power point presentations, software-based “how to” modules
  - Mobile-friendly
  - **www.fda.gov/CDRHLearn**

CDRH Learn - www.fda.gov/CDRHLearn



U.S. FOOD & DRUG ADMINISTRATION

Search | Menu

Home / Training and Continuing Education / CDRH Learn

CDRH Learn

Share | Tweet | LinkedIn | Email | Print

CDRH Learn

CDRH Learn Course List (Spanish)

Welcome to CDRH Learn, FDA's Center for Devices and Radiological Health (CDRH) web page for multimedia industry education. 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. This tool is intended to provide industry with information that is comprehensive, interactive, and easily accessible. Modules are provided in various formats, including videos, audio recordings, and slide presentations. CDRH will determine the most appropriate format for the particular topic being presented, and will post the learning module on this site to meet your educational needs!

Content current as of:
06/01/2021

Help us improve CDRH Learn - take our survey now!

- CDRH Learn Survey

Resources For You

- Device Advice
- Upcoming Medical Device Webinars and Stakeholder Calls
- Subscribe to CDRH Mailing Lists
- Follow Us on Twitter
- Division of Industry and Consumer Education (DICE)

Start Here/The Basics!
MDUFA Small Business Program, Registration and Listing

How to Study and Market Your Device - *(New module 5/20/21)*
510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification

Postmarket Activities - *(New modules 4/15/21)*
Quality System, Exporting, Device Recalls, MDR, Inspection - Global Harmonization

Unique Device Identification (UDI) System

Specialty Technical Topics - *(Updated module 6/1/21)*

Radiation-Emitting Products

510(k) Third Party Review Program (for Third Party Review Organizations)

Industry Basics Workshop Series

DICE Educational Resources

- Regulatory Education for Industry (REdI)
  - Free annual conference
  - Collaboration with the Center for Drug Evaluation and Research (CDER) & CDRH

- Industry Basics
  - Webinar
  - Live question and answer session

DICE Educational Resources

- www.fda.gov/DICE
- www.fda.gov/DeviceAdvice
- www.fda.gov/CDRHLearn
- REdI Workshop webpage

Contact DICE

- **Phone: (800) 638-2041**
  We are available: M-F
  9:00 AM –12:30 PM
  1:00-4:30 PM

- **Email: DICE@fda.hhs.gov**
  Respond within 2 business days

We are here to help YOU!

Use These Public Databases

- **Medical device databases**
  - Access to the MAUDE, MDR, and MedSun reporting databases for adverse event reporting
  - Access to premarket notifications [510(k)s]
  - Product Classifications (product codes) that correlate to respective regulations and recognized consensus standards
  - Recognized consensus standards database
  - Registration & listing
  - Total product life cycle (TPLC) database

Be Aware of Codified Guidance

- **Guidance Documents Database**
  - The most recent recommendations by CDRH for specific device types and submissions (not CFR)
- **Class II Special Controls Documents**
  - Codified (CFR) special controls for class II device submissions [510(k)] that look like Guidance Documents

When In Doubt: Contact DICE

- **Phone: (800) 638-2041**

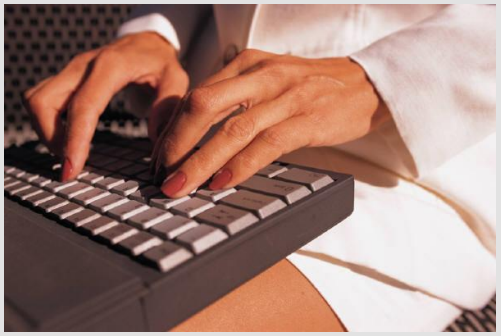
  We are available: M-F

  9:00 AM –12:30 PM

  1:00-4:30 PM

- **Email: DICE@fda.hhs.gov**

  Respond within 2 business days



We are here to help YOU!

Guidance Resources

- Guidance Documents provide non-binding information that represents the agency's current thinking on a topic.
- An alternative approach may be used if such approach satisfies the requirements of the applicable statue, regulations, or both.
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents

MDR Guidance Document

- https://www.fda.gov/media/86420/download

This guidance document describes and explains FDA's current regulation that addresses reporting and recordkeeping requirements applicable to manufacturers of medical devices for device-related adverse events and malfunctions.

MDR Requirements

- https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities#:~:text=Mandatory%20Medical%20Device%20Reporting%3A,product%20problems%20to%20the%20FDA.

MDR Regulation

- The Medical Device Reporting (MDR) regulation (21 CFR Part 803) contains mandatory requirements for manufacturers, importers, and device user facilities to report certain device-related adverse events and product problems to the FDA. The regulation specified that reports be filed on the FDA's Medwatch Form 3500A or an electronic equivalent.
- The FDA published a final rule on Feb. 14, 2014, requiring manufacturers and importers to submit MDRs to the FDA in an electronic format that the FDA can process, review, and archive. This rule was effective Aug.14, 2015.

MDR Contacts

For Questions about Medical Device Reporting, including interpretation of MDR policy:

- Call: (301) 796-6670
- Email: MDRPolicy@fda.hhs.gov

Device Shortage Guidance Document

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc

Device Shortage Contacts

- To submit a notification, please send your information to CDRHManufacturerShortage@fda.hhs.gov and please begin the email subject line with the word "Notification."
- If you have questions about this guidance, contact CDRHManufacturerShortage@fda.hhs.gov and please begin the email subject line with the word "Question" to expedite our response to your question.

Summary

- Utilize DICE Educational Resources
- Contact DICE
- Attend REdI and Industry Basics
- Utilize FDA Guidance Documents

Questions & Answers