U.S. FOOD & DRUG ADMINISTRATION

Division of Industry and Consumer Education (DICE)

2018 OIR 510(k) Submissions Workshop
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Center for Devices and Radiological Health

Complex, Time Consuming, Costly

DICE Mission Statement

Educate medical device industry and consumers with understandable and accessible science-based regulatory information.

We:

- stay current on regulatory issues
- anticipate stakeholder needs
- ensure information is accurate, timely and meets audience needs

Where to Start - FDA.gov

- **Device Advice – Text-Based Education**
  - comprehensive regulatory information on premarket and postmarket topics
  - www.fda.gov/DeviceAdvice
- **CDRH Learn – Multi-Media Industry Education**
  - over 130 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

Device Advice

www.fda.gov/DeviceAdvice

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

Information-Medical Devices / Radiation Products
Division of Industry and Consumer Education
CDRH-Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

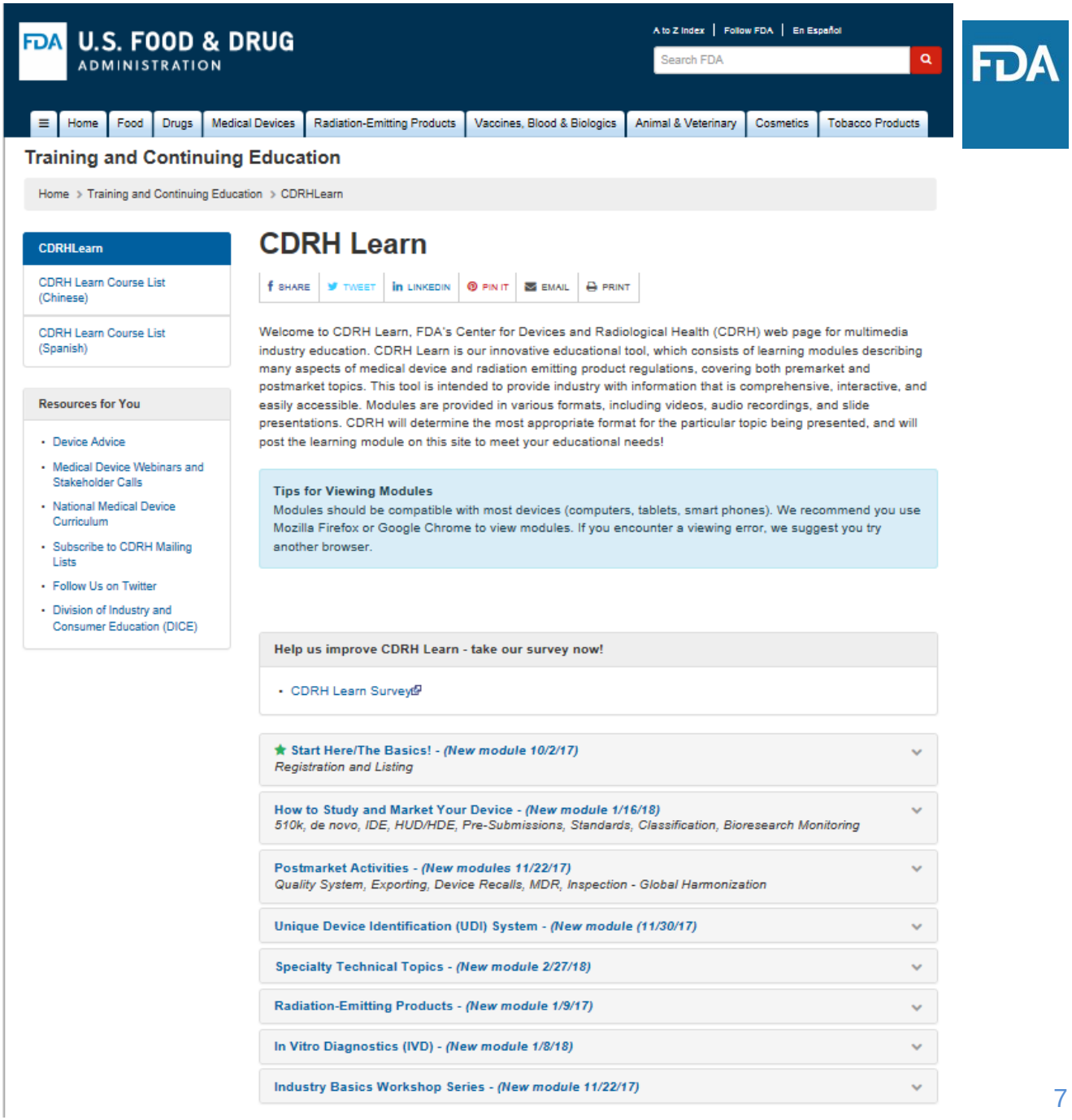
Device Advice

www.fda.gov/DeviceAdvice

- written web content
- 280 pages of premarket/postmarket regulatory information
- divided into approximately 30 categories of content

CDRH Learn

www.fda.gov/Training/CDRHLearn



CDRH Learn

www.fda.gov/Training/CDRHLearn

- over 130 modules
- multi-media, video training modules
- presentations; computer-based training; webinars

What to do next - Contact DICE

- **Phone:** **(800) 638-2041**
  - hours of operation:
    - 9 am–12:30 pm; 1-4:30 pm

- **Email:** **dice@fda.hhs.gov**
  - respond within 2 business days

DICE is here to help YOU!

www.fda.gov/DICE

DICE Stakeholder Inquiries (FY 17)

21,189

12,245

- **Total: 33,434 [average 110/day]**
  - **industry: 24,269**
  - **consumer: 9,165**

DICE Division Expertise

- various **Professional Backgrounds**
  - Biological sciences, engineering, clinical and legal
- advanced **Degrees**
  - PhD, Masters, MD and JD
- **Industry and FDA** experience
  - CDRH, CDER
  - Various offices in CDRH, In Vitro diagnostics, Device Evaluation, Compliance, Science and Engineering, Surveillance and Biometrics
- experience in **DICE**
  - Ranging from 1 to 40 years

Premarket Topics

- how do I market a device
- device classification
- registration and listing (initial)
- premarket applications (510(k), pre-submissions, IDE, De Novo, PMA)
- user fees
- FDA laws, regulations, guidance, and policies

Postmarket Topics

- quality system (manufacturing)
- reporting of adverse effects
- changes to existing devices, including ownership
- recalls and corrections
- import issues (detention of devices)
- export issues and export certificates
- registration and listing (annual)

IVD Topics

- IVD reagents and instrumentation
- CLIA and CLIA determinations
- IVD labeling (21 CFR 809.10)
- use of symbols
- IDE vs. exemption of IDE application
- companion diagnostics

DICE Industry Education

- Regulatory Education for Industry (REdI) Workshop Series
- Industry Basics

Education for Industry (REdI) Workshop Series- **Free**

- 2018 Spring Workshop May 15-16 in San Francisco, CA and live webcast – https://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm602714.htm
  - co-sponsored with CDER/DDI (equivalent to DICE)
  - SMEs from FDA (CDER, CDRH, ORA)
  - regulatory basics and hot/advanced topics
  - Anyone in device regulatory arena (new start-up or established)

Industry Basics

- **Format:**
  - Presentation
  - Live moderated in-studio Q+A session (calls, emails)
  - 120 minutes (two topics)


SMALL
BUSINESS

How many people work for a company that in the past year has gross sales/receipts of less than 100 million dollars?

How many people work for a company that in the past year has gross sales/receipts of less than 30 million dollars?

What is a Small Business?

- An business that reported
  - **$100 million or less** of **gross receipts or sales** in its most recent Federal Income Tax Return for a taxable year
  - Including **all affiliates**

Benefit

- **Reduced fee**
  - PMR
  - Original PMA/BLA
  - PMA/BLA Supplements
    - PMA Supplements: Panel-track, 180-day, & Real-time
    - 30-day Notices
    - Periodic Reports (the annual fee)
  - 510(k)
  - 513(g)
  - De Novo

Benefit

- **Fee Waiver** for first PMA/BLA or PMR
  - Less than **$30 million gross sales/receipts**

FY 18 User Fees (in U.S. Dollars)

Application Type	Standard Fee	Small Business Fee
510(k)	$10,566	$2,642
513(g)	$4,195	$2,098
De Novo Classification	$93,229	$23,307
PMA, PDP, PMR, BLA	$310,764	$77,691◆
Panel-track Supplement	$233,073	$58,268
180-day Supplement	$46,615	$11,654
Real-time Supplement	$21,753	$5,438
BLA Efficacy Supplement	$310,764	$77,691
PMA Annual Report	$10,877	$2,719
30-day Notice	$4,972	$2,486

◆Fee Waiver - Less than 30 million gross sales/receipts

Obtain Your SBD Certification BEFORE You Submit a Premarket Application

Provide Resources

- **Guidance:**
  - FY 2018 Medical Device User Fee Small Business Qualification and Certification

- **Device Advice**:
  - Reduced Medical Device User Fees: Small Business Determination (SBD) Program

If you are eligible, submit your application

Your Call to Action

- Use the FDA website, Device Advice and CDRH Learn
- Contact DICE with **ANY** and **ALL** general device regulatory questions
- Attend REdI and Industry Basics
- Submit Small Business Certification Application

We Are Here to Help

www.fda.gov/MedicalDevices/DICE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