

Division of Industry and Consumer Education (DICE)

2018 OIR 510(k) Submissions Workshop
April 16, 2018

Donna Headlee

Branch Chief

Premarket Programs Branch

Division of Industry and Consumer Education

Office of Communication and Education

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

[f SHARE](#)
[t TWEET](#)
[in LINKEDIN](#)
[p PIN IT](#)
[e EMAIL](#)
[p 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) 798-7100
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

**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

Training and Continuing Education

Home > Training and Continuing Education > CDRHLearn

CDRHLearn

[CDRH Learn Course List \(Chinese\)](#)

[CDRH Learn Course List \(Spanish\)](#)

Resources for You

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

CDRH Learn

[f SHARE](#) [t TWEET](#) [in LINKEDIN](#) [p PIN IT](#) [e EMAIL](#) [p PRINT](#)

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!

Tips for Viewing Modules

Modules should be compatible with most devices (computers, tablets, smart phones). We recommend you use Mozilla Firefox or Google Chrome to view modules. If you encounter a viewing error, we suggest you try another browser.

Help us improve CDRH Learn - take our survey now!

[• CDRH Learn Survey](#)

[★ Start Here/The Basics! - \(New module 10/2/17\)](#)
Registration and Listing

[How to Study and Market Your Device - \(New module 1/16/18\)](#)
510k, de novo, IDE, HUD/HDE, Pre-Submissions, Standards, Classification, Bioresearch Monitoring

[Postmarket Activities - \(New modules 11/22/17\)](#)
Quality System, Exporting, Device Recalls, MDR, Inspection - Global Harmonization

[Unique Device Identification \(UDI\) System - \(New module 11/30/17\)](#)

[Specialty Technical Topics - \(New module 2/27/18\)](#)

[Radiation-Emitting Products - \(New module 1/9/17\)](#)

[In Vitro Diagnostics \(IVD\) - \(New module 1/8/18\)](#)

[Industry Basics Workshop Series - \(New module 11/22/17\)](#)





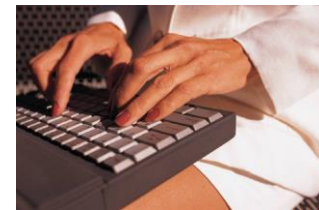
CDRH Learn

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

coming soon

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)





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 REdl and Industry Basics
- Submit Small Business Certification Application

We Are Here to Help



www.fda.gov/MedicalDevices/DICE

