

# **Navigating the Medical Device Regulatory Framework Utilizing CDRH Resources**

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

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# Learning Objectives

- Discuss medical device legislation and CDRH's organization
- Define medical device and radiation emitting product
- Identify the steps to market a new medical device
- Discuss additional need to know resources

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# Key Medical Device Legislation

- 1938 [Federal Food, Drug, and Cosmetic Act \(FD&C Act\)](#)
- 1976 [Medical Device Amendments of 1976](#)
- 2002 [Medical Device User Fee and Modernization Act](#)
- **2023** [\*\*Medical Device User Fee Amendments\*\*](#)  
(MDUFA V) (effective Oct. 1, 2022)

**\*Coming  
Soon**

**NEED TO KNOW**

- [MDUFA Reports](#)

# U.S.C. vs. FD&C Act vs. Regulations

- United States Code (U.S. Code)
- FD&C Act
- Code of Federal Regulations (CFR)
- Federal Register

## NEED TO KNOW

- [U.S. Code](#)
- [CFR Search \(CFR Title 21\)](#)
- [Electronic Code of Federal Regulations \(eCFR\)](#)
- [Regulations.gov](#)

# CDRH's Mission

- Assure access to **safe, effective, and high-quality** products
- Provide **understandable** and accessible **science-based information**
- Facilitate **innovation** and assure consumer **confidence**

# CDRH

Office of the Center Director

FDA

Office of Communication and Education

Office of Management

Office of Policy

Office of Product Evaluation and Quality

Office of Science and Engineering Laboratories

Office of Strategic Partnerships and Technology Innovation



# Office of Health Technology (OHT)

Office Title	Product Area
OHT1	Ophthalmic, Anesthesia, Respiratory, Ear, Nose and Throat (ENT), Dental
OHT2	Cardiovascular
OHT3	Gastro-renal, Obstetrics and Gynecology, General Hospital, Urology
OHT4	Surgical, Infection Control
OHT5	Neurological, Physical Medicine
OHT6	Orthopedic
OHT7	In Vitro Diagnostics
OHT8	Radiological Health

**\*Recent Change**

**NEED TO KNOW**

• [CDRH Management Directory](#)

# Want Updates?

**NEED  
TO  
KNOW**

- [FDA.gov/Medical Devices](https://www.fda.gov/medical-devices)
- [\[FDA\] Get Email Updates](#)
- [Subscribe to CDRH Email Lists](#)
- [CDRHNew – News and Updates](#)

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# Medical Device Definition

- Intended for:
  - **diagnosis** of disease or other conditions
  - or **cure, mitigation, treatment, or prevention** of disease
  - or to affect the **structure** or any **function** of the body

# Medical Device Definition (continued)

- Does **NOT achieve** its primary intended purposes **through chemical action** or dependent on being **metabolized**
- Does **NOT** include **certain software functions** excluded pursuant to section 520(o).

# Medical Device Definition

**NEED  
TO  
KNOW**

- [21 U.S.C. 321\(h\)](#)
- [How to Determine if Your Product is a Medical Device](#)
- [CDRH Learn Module: Is My Product a Medical Device?](#)

# In Vitro Diagnostics (IVDs)

- **Reagents, instruments, and systems** intended for use in the diagnosis of disease or other conditions.
- Examples: Home Pregnancy Test, Glucose Test Strip

**NEED TO KNOW**

- [In Vitro Diagnostics \[Homepage\]](#)

# Radiation Emitting Products

- When in operation (i) contains or acts as part of an **electronic circuit** and (ii) **emits electronic product radiation**
- Examples: Diagnostic Ultrasound, X-Rays, Medical Lasers

## NEED TO KNOW

- [Radiation-Emitting Products Industry Assistance: Walk-through](#)
- [Getting a Radiation Emitting Product to Market: FAQs](#)



# Knowledge Check

**A radiation emitting product must only comply with the radiation safety regulations.**

1. True
2. False
3. It Depends

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## NEED TO KNOW

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

1

Classify Your Device and Understand Applicable Regulatory Controls

2

Select and Prepare the Correct Premarket Submission

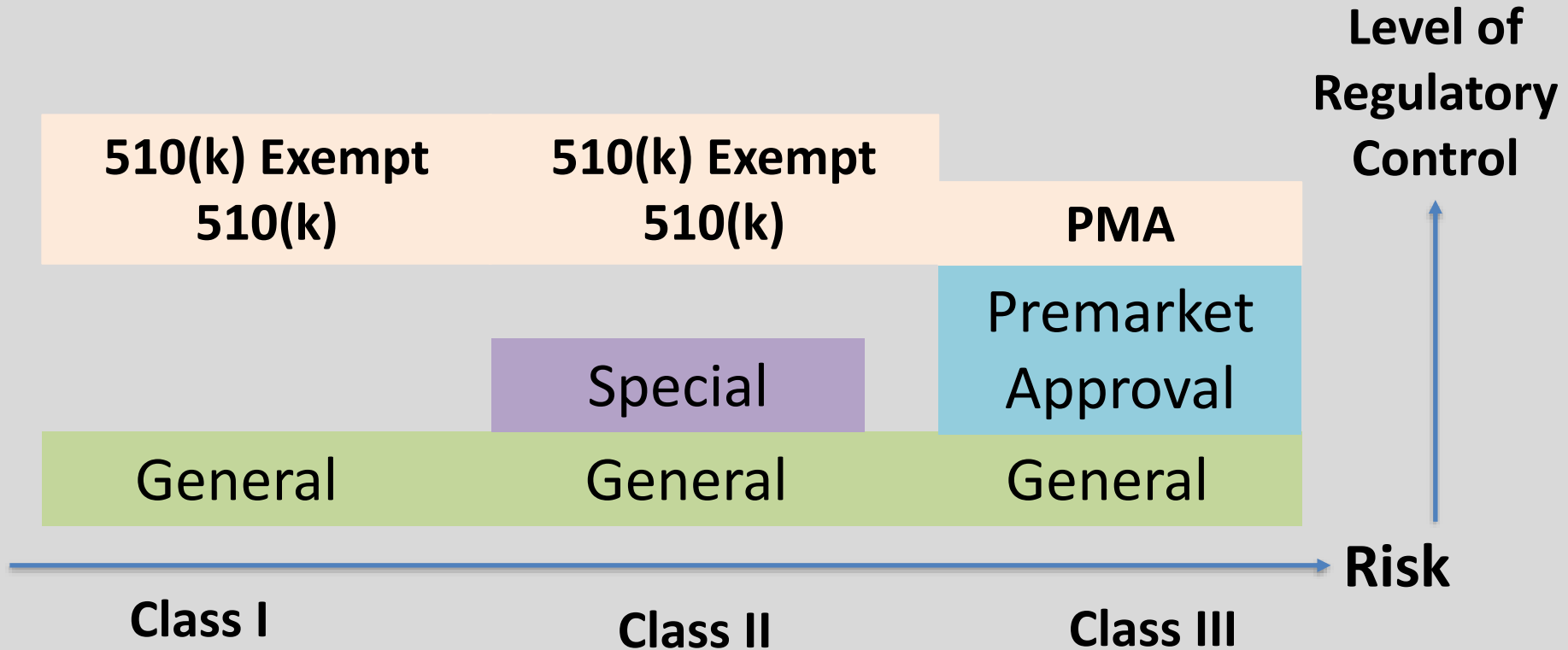
3

Send your Premarket Submission to the FDA

4

Comply with Applicable Regulatory Controls Including Establishment Registration and Device Listing

# Classification & Regulatory Controls



# Classification & Regulatory Controls

**NEED  
TO  
KNOW**

- [Classify Your Medical Device](#)
- [Class I and Class II Device Exemptions](#)
- [Regulatory Controls](#)
- [CDRH Learn – How is My Medical Device Classified?](#)
- [Product Classification Database](#)

# NEED TO KNOW

## • Product Classification

### Product Classification

◀ FDA Home ▶ Medical Devices ▶ Databases

This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA Premarket Review organizations, and other regulatory information.

[learn more...](#)

#### Search Database



Help



Download Files

Device

Product Code

Review Panel

Regulation Number

Submission Type

Third Party Eligible

Implanted Device

Life-Sustain/Support Device

Device Class

Summary Malfunction Reporting

[Go to Quick Search](#)

[Clear Form](#)

search

# Premarket Submissions

**NEED  
TO  
KNOW**

- [Premarket Submissions: Selecting and Preparing the Correct Submission](#)
- [Guidance Documents](#)
  - [The Q-Submission Program Guidance](#)
- [Class II Special Controls Documents](#)
- [Recognized Consensus Standards](#)
- [CDRH FOIA](#)

# NEED TO KNOW

## • [510\(k\) Premarket Notification Database](#)

### 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...](#)

#### Search Database



Help



Download Files

510K Number

Type

Product Code

Center

Combination Products

☐

Applicant Name

Cleared/Approved in Vitro Products

☐

Device Name

Redacted FOIA 510(k) ☒

Panel

Decision

Decision Date



to



Clinical Trials

☐

Sort by

Decision Date (descending)

[Quick Search](#)

[Clear Form](#)

Search



# Premarket Submissions (cont.)

**NEED  
TO  
KNOW**

- [FDA Forms](#)
- [eCopy Program](#)
- [eSTAR Program](#)
- [Medical Device User Fees](#)
- [Reduced Medical Device User Fees: Small Business Determination \(SBD\) Program](#)
- [Progress Tracker](#)

# Continued Compliance

**NEED  
TO  
KNOW**

- Postmarket Requirements (Devices)
- Establishment Registration and Device Listing
- Quality System Regulation
- Medical Device Reporting/eMDR
- Medical Device Tracking

# Knowledge Check

Should I register my device when I submit my 510(k)?

1. Yes
2. No
3. It depends

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**NEED TO KNOW****• Device Advice**

- Written content
- Over 300 pages of total product life cycle regulatory information
- Over 30 regulatory categories

**NEED TO KNOW**• **CDRH Learn**

- Multi-media video training modules
- Presentations, computer-based training, webinars
- Approximately 200 modules (most ~ 20 min)
- Mobile-friendly

**NEED TO KNOW**

- [Division of Industry and Consumer Education](#)

**Phone:** [\(800\) 638-2041](tel:(800)638-2041)

- Hours of Operation: 9 AM – 12:30 PM; 1 – 4:30 PM ET

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

- DICE will respond within 2 business days

# Resources

Slide Number	Cited Resource	URL
5	Federal Food, Drug, and Cosmetic Act (FD&C Act)	<a href="http://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act">www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act</a>
5	Medical Device Amendment of 1976	<a href="http://www.govinfo.gov/content/pkg/STATUTE-90/pdf/STATUTE-90-Pg539.pdf">www.govinfo.gov/content/pkg/STATUTE-90/pdf/STATUTE-90-Pg539.pdf</a>
5	Medical Device User Fee and Modernization Act	<a href="http://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-and-modernization-act-2002-mdufma">www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-and-modernization-act-2002-mdufma</a>
5	Medical Device User Fee Amendments	<a href="http://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v">www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v</a>



# Resources

Slide Number	Cited Resource	URL
5	MDUFA Reports	<a href="http://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-reports">www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-reports</a>
6	U.S. Code	<a href="http://uscode.house.gov/browse.xhtml">uscode.house.gov/browse.xhtml</a>
6	CFR Search (CFR Title 21)	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm</a>
6	Electronic Code of Federal Regulations (eCFR)	<a href="http://www.ecfr.gov/current/title-21">www.ecfr.gov/current/title-21</a>
6	Regulations.gov	<a href="http://www.regulations.gov/">www.regulations.gov/</a>

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7	CDRH Management Directory	<a href="http://www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization">www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization</a>
10	FDA.gov/Medical Devices	<a href="http://www.fda.gov/Medical-Devices">www.fda.gov/Medical-Devices</a>
10	[FDA] Get Email Updates	<a href="http://www.fda.gov/about-fda/contact-fda/get-email-updates">www.fda.gov/about-fda/contact-fda/get-email-updates</a>
10	Subscribe to CDRH Email Lists	<a href="http://www.fda.gov/about-fda/center-devices-and-radiological-health/subscribe-cdrh-email-lists">www.fda.gov/about-fda/center-devices-and-radiological-health/subscribe-cdrh-email-lists</a>
10	CDRHNew – News and Updates	<a href="http://www.fda.gov/medical-devices/news-events-medical-devices/cdrhnew-news-and-updates">www.fda.gov/medical-devices/news-events-medical-devices/cdrhnew-news-and-updates</a>

# Resources

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14	21 U.S.C. 321(h)	<a href="https://uscode.house.gov/view.xhtml?req=(title:21%20section:321%20edition:prelim)%20OR%20(granuleid:USC-prelim-title21-section321)&amp;f=treesort&amp;edition=prelim&amp;num=0&amp;jumpTo=true">uscode.house.gov/view.xhtml?req=(title:21%20section:321%20edition:prelim)%20OR%20(granuleid:USC-prelim-title21-section321)&amp;f=treesort&amp;edition=prelim&amp;num=0&amp;jumpTo=true</a>
14	How to Determine if Your Product is a Medical Device	<a href="https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device">www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device</a>
14	CDRH Learn Module: Is My Product a Medical Device?	<a href="https://fda.yorkcast.com/webcast/Play/e0eec5f6ee3d4947a70fcede-f32993f71d">fda.yorkcast.com/webcast/Play/e0eec5f6ee3d4947a70fcede-f32993f71d</a>
15	In Vitro Diagnostics [Homepage]	<a href="https://www.fda.gov/medical-devices/products-and-medical-procedures/in-vitro-diagnostics">www.fda.gov/medical-devices/products-and-medical-procedures/in-vitro-diagnostics</a>

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16	Radiation-Emitting Products Industry Assistance: Walk-through	<a href="http://www.fda.gov/radiation-emitting-products/getting-radiation-emitting-product-market-frequently-asked-questions/radiation-emitting-products-industry-assistance-walk-through">www.fda.gov/radiation-emitting-products/getting-radiation-emitting-product-market-frequently-asked-questions/radiation-emitting-products-industry-assistance-walk-through</a>
16	Getting a Radiation Emitting Product to Market: FAQs	<a href="http://www.fda.gov/radiation-emitting-products/electronic-product-radiation-control-program/getting-radiation-emitting-product-market-frequently-asked-questions">www.fda.gov/radiation-emitting-products/electronic-product-radiation-control-program/getting-radiation-emitting-product-market-frequently-asked-questions</a>
20	How to Study and Market Your Device	<a href="http://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device">www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device</a>

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22	Classify Your Medical Device	<a href="http://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device">www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device</a>
22	Class I and Class II Device Exemptions	<a href="http://www.fda.gov/medical-devices/classify-your-medical-device/class-i-and-class-ii-device-exemptions">www.fda.gov/medical-devices/classify-your-medical-device/class-i-and-class-ii-device-exemptions</a>
22	Regulatory Controls	<a href="http://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls">www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls</a>
22	CDRH Learn – How is My Medical Device Classified?	<a href="http://fda.yorkcast.com/webcast/Play/17792840509f49f0875806b6e9a1be471d">fda.yorkcast.com/webcast/Play/17792840509f49f0875806b6e9a1be471d</a>

# Resources

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22, 23	Product Classification Database	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm</a>
24	Premarket Submissions: Selecting and Preparing the Correct Submission	<a href="http://www.fda.gov/medical-devices/how-study-and-market-your-device/premarket-submissions">www.fda.gov/medical-devices/how-study-and-market-your-device/premarket-submissions</a>
24	Guidance Documents	<a href="http://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products">www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products</a>
24	The Q-Submission Program Guidance	<a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program">www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program</a>

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Slide Number	Cited Resource	URL
24	Class II Special Controls Documents	<a href="http://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/class-ii-special-controls-documents">www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/class-ii-special-controls-documents</a>
24	Recognized Consensus Standards	<a href="http://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/standards-and-conformity-assessment-program">www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/standards-and-conformity-assessment-program</a>
24	CDRH FOIA	<a href="http://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-foia-how-get-records-cdrh">www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-foia-how-get-records-cdrh</a>
25	510(k) Premarket Notification	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm</a>

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26	FDA Forms	<a href="http://www.fda.gov/about-fda/reports-manuals-forms/forms">www.fda.gov/about-fda/reports-manuals-forms/forms</a>
26	eCopy Program	<a href="http://www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-program-medical-device-submissions">www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-program-medical-device-submissions</a>
26	eSTAR Program	<a href="http://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program">www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program</a>
26	Medical Device User Fees	<a href="http://www.fda.gov/medical-devices/premarket-submissions/medical-device-user-fees">www.fda.gov/medical-devices/premarket-submissions/medical-device-user-fees</a>
26	Reduced Medical Device User Fees: Small Business Determination (SBD) Program	<a href="http://www.fda.gov/medical-devices/premarket-submissions/reduced-medical-device-user-fees-small-business-determination-sbd-program">www.fda.gov/medical-devices/premarket-submissions/reduced-medical-device-user-fees-small-business-determination-sbd-program</a>



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26	Progress Tracker	<a href="http://www.fda.gov/medical-devices/industry-medical-devices/tracking-your-premarket-submissions-progress-progress-tracker">www.fda.gov/medical-devices/industry-medical-devices/tracking-your-premarket-submissions-progress-progress-tracker</a>
27	Postmarket Requirements (Devices)	<a href="http://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/postmarket-requirements-devices">www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/postmarket-requirements-devices</a>
27	Establishment Registration and Device Listing	<a href="http://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing">www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing</a>
27	Quality System Regulation	<a href="http://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices">www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices</a>

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27	Medical Device Reporting/eMDR	<a href="http://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities">www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities</a>
27	Medical Device Tracking	<a href="http://www.fda.gov/medical-devices/postmarket-requirements-devices/medical-device-tracking">www.fda.gov/medical-devices/postmarket-requirements-devices/medical-device-tracking</a>
31	Device Advice	<a href="http://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance">www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance</a>
32	CDRH Learn	<a href="http://www.fda.gov/training-and-continuing-education/cdrh-learn">www.fda.gov/training-and-continuing-education/cdrh-learn</a>
33	DICE	<a href="http://www.fda.gov/DICE">www.fda.gov/DICE</a>

# Summary

- Key legislation ensures access to **safe, effective, and high-quality** products
- The **risk** of a device determines the extent of **regulatory controls**
- There are **four main steps** to bring a new device to market
- Available **resources** can help you navigate the regulatory framework

# Questions

