

Is My Product a Medical Device?

CDR Kimberly Piermatteo, MHA

Consumer Safety Officer

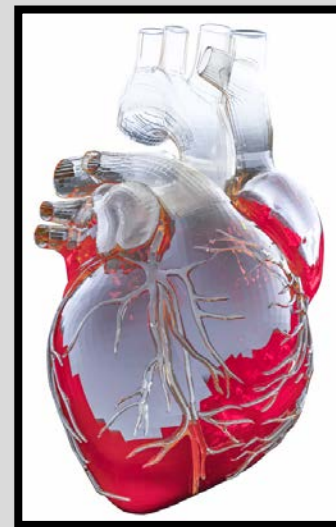
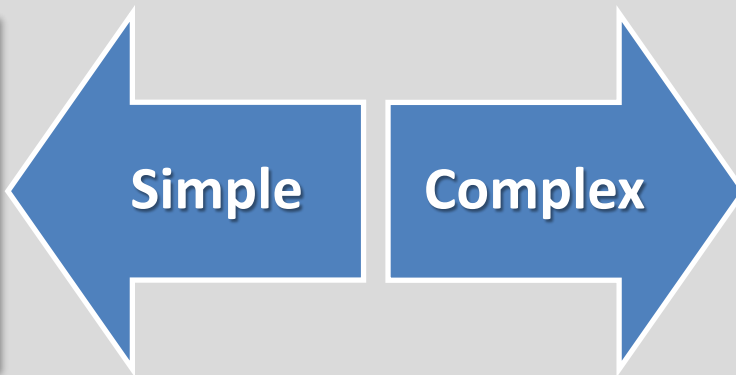
Division of Industry and Consumer Education

Office of Communication and Education

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Medical Devices Are Diverse



Learning Objectives

1. Define what is a medical device
2. Discuss special considerations
3. Discuss an example of a device determination
4. Identify ways to request further assistance

Definition of a Medical Device

Definition of a Medical Device

Section 201(h) of the Food, Drug & Cosmetic Act (FD&C Act) defines a device as:

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:

Definition of a Medical Device

(Continued)

- recognized in the **official National Formulary**, or the **United States Pharmacopoeia**, or any supplement to them,
- intended for use in the **diagnosis** of disease or other conditions, or in the **cure, mitigation, treatment**, or **prevention of disease** in man or other animals, or
- intended to **affect the structure or any function** of the body of man or other animals

Definition of a Medical Device

(Continued)

- And does not achieve its primary intended purposes through **chemical action** within or on the body of man or other animals and which is not dependent upon being **metabolized** for the achievement of its primary intended purposes.
- The term "device" does not include software functions excluded pursuant to section 520(o).

Examples of Excluded Software

Per Section 520(o)

- Administrative support of a health care facility;
- Maintaining or encouraging a healthy lifestyle unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;
- Serve as electronic patient records; or
- Transferring, storing, converting formats, or displaying test or other device data, results or findings but not intended to interpret or analyze them.

Know Your Product

- What is the **intended use** of your product?
- How does your product **function**?
- What **claims** do you intend to make?



Defining Your Intended Use is Key!

- Clearly state the **general purpose** or its **function**
- Further describe:
 - The **disease or condition** the product will diagnose, cure, mitigate, treat or prevent
 - The intended **patient population**



Is There an Existing Product Classification?

Product Classification Database

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 <input style="width: 90%;" type="text"/>	Product Code <input style="width: 90%;" type="text"/>
Review Panel <input style="width: 90%;" type="text"/>	Regulation Number <input style="width: 90%;" type="text"/>
Submission Type <input style="width: 90%;" type="text"/>	Third Party Eligible <input style="width: 90%;" type="text"/>
Implanted Device <input style="width: 90%;" type="text"/> Life-Sustain/Support Device <input style="width: 90%;" type="text"/>	Device Class <input style="width: 90%;" type="text"/>
Summary Malfunction Reporting <input style="width: 90%;" type="text"/>	

[Go to Quick Search](#)
[Clear Form](#)

Product Classification Database:

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpdc/classification.cfm

Special Considerations

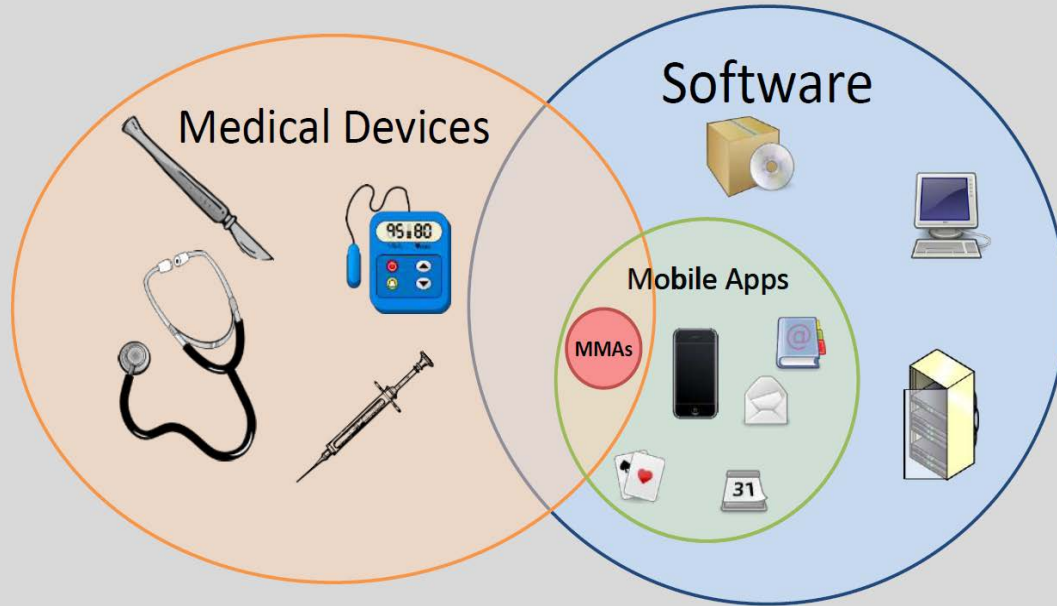
In Vitro Diagnostics (IVDs)

- **Reagents, instruments, and systems** intended for use in the diagnosis of disease or other conditions.
 - **Collect, prepare, and examine specimens** taken from the human body
 - Can be used in **a laboratory, health professional setting or at home**
- Examples: Home Pregnancy Test, Glucose Test Strip

Radiation Emitting Products

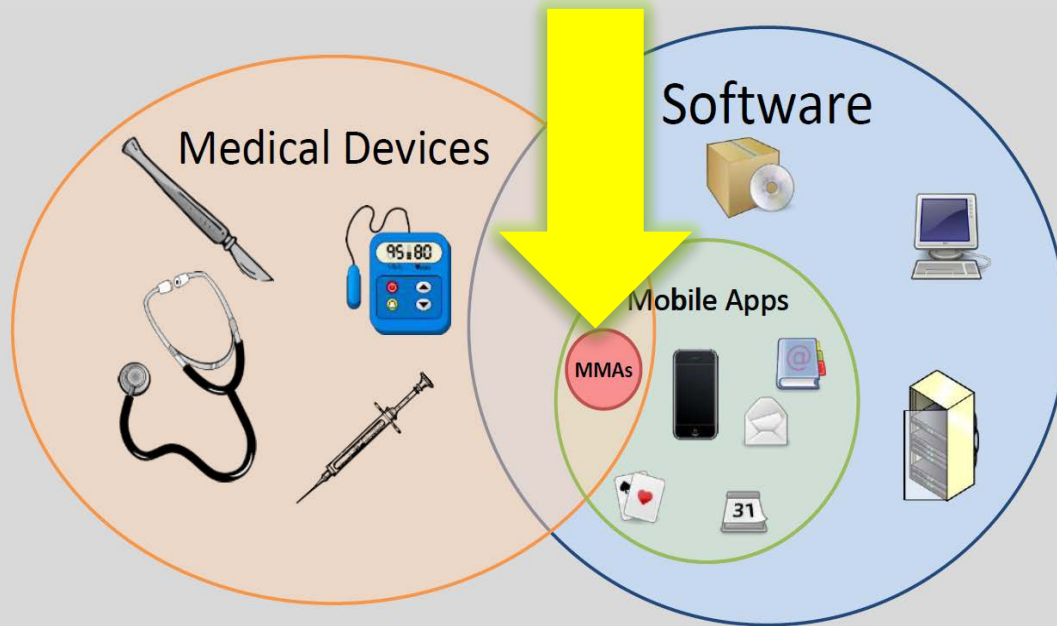
- **Section 531** of the FD&C Act defines an electronic product as a product which when in operation (i) contains or acts as part of an **electronic circuit** and (ii) **emits electronic product radiation**
 - Most radiation-emitting products are not medical devices
 - Some radiation-emitting products with medical applications and claims meet the definition of medical device
- Examples: Diagnostic Ultrasound, X-Rays, Medical Lasers

Mobile Medical Applications



Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications:
www.fda.gov/regulatory-information/search-fda-guidance-documents/mobile-medical-applications

Mobile Medical Applications



Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications:
www.fda.gov/regulatory-information/search-fda-guidance-documents/mobile-medical-applications

Software as a Medical Device (SaMD)

- SaMD defined as:
 - **“software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device”**
- Example: Software that allows a smartphone to view images obtained from a magnetic resonance imaging (MRI) medical device for diagnostic purposes

General Wellness Products

Products must meet the following two factors:

1. Are intended for only general wellness use, as defined in the guidance, and
2. Present a very low risk to users' safety.

Guidance for Industry and Food and Drug Administration Staff - General Wellness: Policy for Low Risk Devices:

www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices

Combination Products

- 21 CFR 3.2(e): Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products
- Lead center is based on a determination of the “primary mode of action” (PMOA)
- Examples: Drug Eluting Stent, Heparin Coated Dialysis Catheter, First-Aid Kit with a Drug

Products Regulated by Other FDA Centers

- Center for Drug Evaluation and Research (CDER):
www.fda.gov/drugs
- Center for Biologics Evaluation and Research (CBER):
www.fda.gov/vaccines-blood-biologics
- Center for Veterinary Medicine (CVM):
www.fda.gov/animal-veterinary
- Center for Tobacco Products (CTP):
www.fda.gov/tobacco-products

Device Determination Example

Which product is a medical device?

Adult Diaper



VS.

Infant Diaper



Define the Intended Use

Adult Diaper



Intended to protect an adult's garments from urine or stool.

VS.

Infant Diaper



Intended to protect an infant's garments from urine or stool.

Further Define the Intended Use

Adult Diaper



Intended to protect an **incontinent** patient's garment from urine or stool.

VS.

Infant Diaper



Intended to protect an infant's garments from urine or stool.

Medical Device Definition Questions

Adult
Diaper

Infant
Diaper

1 Is it intended to **diagnose, cure, mitigate, treat, or prevent disease** in a human?

2 Is it intended to **affect the structure or any function of the body**?

3 Does it achieve its primary intended purpose by **chemical action** or by being **metabolized**?

Medical Device Definition Questions

Adult
Diaper

Infant
Diaper

1 Is it intended to **diagnose, cure, mitigate, treat, or prevent disease** in a human?

Yes

No

2 Is it intended to **affect the structure or any function of the body**?

No

No

3 Does it achieve its primary intended purpose by **chemical action** or by being **metabolized**?

No

No

Medical Device Definition Questions		Adult Diaper	Infant Diaper
1	Is it intended to diagnose, cure, mitigate, treat, or prevent disease in a human?	Yes	No
2	Is it intended to affect the structure or any function of the body ?	No	No
3	Does it achieve its primary intended purpose by chemical action or by being metabolized ?	No	No
Does it meet the definition of a medical device?		Yes	No

Is there an existing product classification?

Adult Diaper



VS.

Infant Diaper



Search the Product Classification Database

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	<input type="text"/>	Product Code	<input type="text"/>
Review Panel	<input type="text"/>	Regulation Number	<input type="text"/>
Submission Type	<input type="text"/>	Third Party Eligible	<input type="text"/>
Implanted Device	<input type="text"/>	Life-Sustain/Support Device	<input type="text"/>
Device Class	<input type="text"/>		
Summary Malfunction Reporting	<input type="text"/>		

[Go to Quick Search](#) Clear Form

Product Classification Database;

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpdc/classification.cfm

Quick Search

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 Product Classification

Search

[Advanced Search](#)

Quick Search

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...](#)

incontinence

Search

[Advanced Search](#)

Quick Search Results

Product Classification

FDA Home > Medical Devices > Databases



1 to 10 of 23 Results
for *incontinence*

1 2 3 >

Results per page 10

[New Search](#)

Export To Excel Help

Product Code	Device	Regulation Number	Device Class	
EXI	Device, Paste-on For Incontinence, Steri ...	Urine Collector And Accessories	876.5250	1
EXJ	Device, Incontinence, Urosheath Type, St ...	Urine Collector And Accessories	876.5250	1
EYQ	Garment, Protective, For Incontinence	Protective Garment For Incontinence	876.5920	1
EZW	Stimulator, Electrical, Implantable, For ...	Implanted Electrical Urinary Continen ...	876.5270	3
EZY	Device, Incontinence, Mechanical/hydraul ...	Implanted Mechanical/hydraulic Urinary C...	876.5280	3
KPI	Stimulator, Electrical, Non-implantable, ...	Nonimplanted Electrical Continen ...	876.5320	2
MIP	Implanted Fecal Incontinence Device			3
MNG	External Urethral Occluder, Urinary Inco ...	Urological Clamp For Males	876.5160	1
MUK	Electrosurgical Radiofrequency System, S ...	Electrosurgical Cutting And Coagulation ...	878.4400	2
NNX	Device, Incontinence, Urosheath Type, No ...	Urine Collector And Accessories	876.5250	1

Quick Search Results

Product Classification

FDA Home > Products > Devices > Databases

1 to 10 of 10 results for incontinence

1 2 3 >

Results per page 10

Export To Excel Help

Product Code	Product Name	Regulation Number	Device Class
EYQ	Garment, Protective, For Incontinence	876.5920	1
KPI	Stimulator, Electrical, Non-implantable, ...	876.5320	2
MIP	Implanted Fecal Incontinence Device		3
MNG	External Urethral Occluder, Urinary Inco ...	876.5160	1
MUK	Electrosurgical Radiofrequency System, S ...	878.4400	2
NXX	Device, Incontinence, Urosheath Type, No ...	876.5250	1

Product Classification “Garment, Protective, For Incontinence”

Device	Garment, Protective, For Incontinence
Regulation Description	Protective garment for incontinence.
Regulation Medical Specialty	Gastroenterology/Urology
Review Panel	Gastroenterology/Urology
Product Code	EYQ
Premarket Review	Gastrorenal, ObGyn, General Hospital, and Urology Devices (OHT3) Reproductive, Gynecology and Urology Devices (DHT3B)
Submission Type	510(K) Exempt
Regulation Number	876.5920
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	Yes
	Note: This device is also exempted from the GMP regulation, except for general requirements concerning records (820.180) and complaint files (820.198), as long as the device is <u>not</u> labeled or otherwise represented as sterile.
Summary Malfunction Reporting	Eligible
	Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the <i>Federal Registers</i> of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892 . Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.
	If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892 , a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

Product Classification “Garment, Protective, For Incontinence”

Device	Garment, Protective, For Incontinence
Regulation Description	Protective garment for incontinence.
Regulation Medical Specialty	Gastroenterology/Urology
Review Panel	Gastroenterology/Urology
Product Code	EYQ
Premarket Review	Gastrorenal, ObGyn, General Hospital, and Urology Devices (OHT3) Reproductive, Gynecology and Urology Devices (DHT3B)
Submission Type	3rd Party Exempt
Regulation Number	876.5920
Device Class	Class I
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	Yes
<p>Note: This device is also exempted from the GMP regulation, except for general requirements concerning records (820.180) and complaint files (820.198), as long as the device is <u>not</u> labeled or otherwise represented as sterile.</p>	
Summary Malfunction Reporting	Eligible
<p>Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the <i>Federal Registers</i> of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.</p> <p>If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.</p>	
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

Regulation Description

“Garment, Protective, For Incontinence”

TITLE 21--FOOD AND DRUGS
 CHAPTER I--FOOD AND DRUG ADMINISTRATION
 DEPARTMENT OF HEALTH AND HUMAN SERVICES
 SUBCHAPTER H--MEDICAL DEVICES

PART 876 -- GASTROENTEROLOGY-UROLOGY DEVICES

Subpart F--Therapeutic Devices

Sec. 876.5920 Protective garment for incontinence.

(a) *Identification.* A protective garment for incontinence is a device that consists of absorbent padding and a fluid barrier and that is intended to protect an incontinent patient's garment from the patient's excreta. This generic type of device does not include diapers for infants.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 876.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of 820.180, regarding general requirements concerning records, and 820.198, regarding complaint files.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25050, June 12, 1989; 66 FR 38802, July 25, 2001]

Regulation Description

“Garment, Protective, For Incontinence”

TITLE 21--FOOD AND DRUGS
 CHAPTER I--FOOD AND DRUG ADMINISTRATION
 DEPARTMENT OF HEALTH AND HUMAN SERVICES
 SUBCHAPTER H--MEDICAL DEVICES

PART 876 -- GASTROENTEROLOGY-UROLOGY DEVICES

Subpart F--Therapeutic Devices

Sec. 876.5920 Protective garment for incontinence.

(a) *Identification.* A protective garment for incontinence is a device that consists of absorbent padding and a fluid barrier and that is intended to protect an incontinent patient's garment from the patient's excreta. This generic type of device does not include diapers for infants.

Regarding Compliance Dates:

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25050, June 12, 1989; 66 FR 38802, July 25, 2001]

Questions	Adult Diaper	Infant Diaper
Is there an existing product classification?	Yes	No
Is the product regulated as a medical device?	Yes	No

Further Assistance

Informal Assistance

- Contact the **Division of Industry and Consumer Education (DICE)**
 - Phone: 1-800-638-2041
 - Email: dice@fda.hhs.gov
- Email the **Device Determination** experts
(DeviceDetermination@fda.hhs.gov)
- ***Responses are not classification decisions and do not constitute FDA clearance or approval for commercial distribution***

Formal Assistance

- Appropriate when a **formal determination** is requested
- Submit a 513(g) Request
 - FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act; www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic
- ***Responses do not constitute FDA clearance or approval for commercial distribution***

Summary

- Medical devices are defined under **Section 201(h) of the FD&C Act**
- A clearly defined **intended use** is key
- Identifying an **existing medical device product classification** can be helpful
- Consider further **assistance** if necessary

Resources

Slide Number	Cited Resource	URL
5	Is the Product A Medical Device?	www.fda.gov/medical-devices/classify-your-medical-device/product-medical-device
12, 27	Product Classification Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/classification.cfm
14	In Vitro Diagnostics [Homepage]	www.fda.gov/medical-devices/products-and-medical-procedures/vitro-diagnostics
14	Overview of IVD Regulation	www.fda.gov/medical-devices/ivd-regulatory-assistance/overview-ivd-regulation
15	Getting a Radiation Emitting Product to Market	www.fda.gov/radiation-emitting-products/electronic-product-radiation-control-program/getting-radiation-emitting-product-market

Resources

Slide Number	Cited Resource	URL
15	Radiation-Emitting Products Industry Assistance: Walk-through	www.fda.gov/radiation-emitting-products/getting-radiation-emitting-product-market/radiation-emitting-products-industry-assistance-walk-through
16	Mobile Medical Applications	www.fda.gov/medical-devices/digital-health/mobile-medical-applications
16	Guidance for Industry and Food and Drug Administration Staff [February 2019] - Mobile Medical Applications	www.fda.gov/regulatory-information/search-fda-guidance-documents/mobile-medical-applications
18	Software as a Medical Device (SaMD)	www.fda.gov/medical-devices/digital-health/software-medical-device-samd

Resources

Slide Number	Cited Resource	URL
19	Guidance for Industry and Food and Drug Administration Staff [July 2016] - General Wellness: Policy for Low Risk Devices	www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices
20	Combination Products	www.fda.gov/combination-products
38	Device – Not a Device	www.fda.gov/medical-devices/classify-your-medical-device/device-not-device
39	FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act	www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic

Providing Industry Education

1. CDRH Learn – Multi-Media Industry Education

- over 100 modules - videos, audio recordings, PowerPoint presentations, software-based “how to” modules
- accessible on your portable devices: www.fda.gov/CDRHLearn

2. Device Advice – Text-Based Education

- comprehensive regulatory information on premarket and postmarket topics: www.fda.gov/DeviceAdvice

3. Division of Industry and Consumer Education (DICE)

- Email: DICE@fda.hhs.gov
- Phone: 1-800-638-2041 or (301) 796-7100 (Live Agents 9 am – 12:30 pm; 1 – 4: 30 pm ET)

Your Call to Action

Familiarize yourself with:

- The **definition of a medical device**; and
- FDA's public **product classification database**



