Is My Product a Medical Device?

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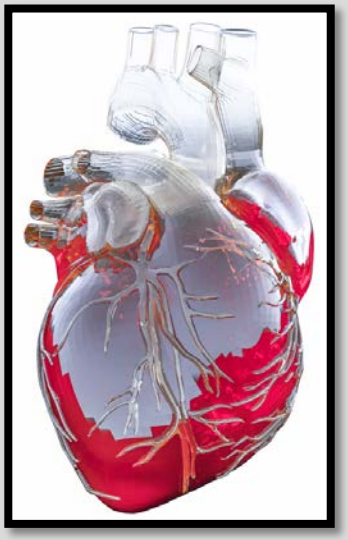
Medical Devices Are Diverse

Simple

Complex



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

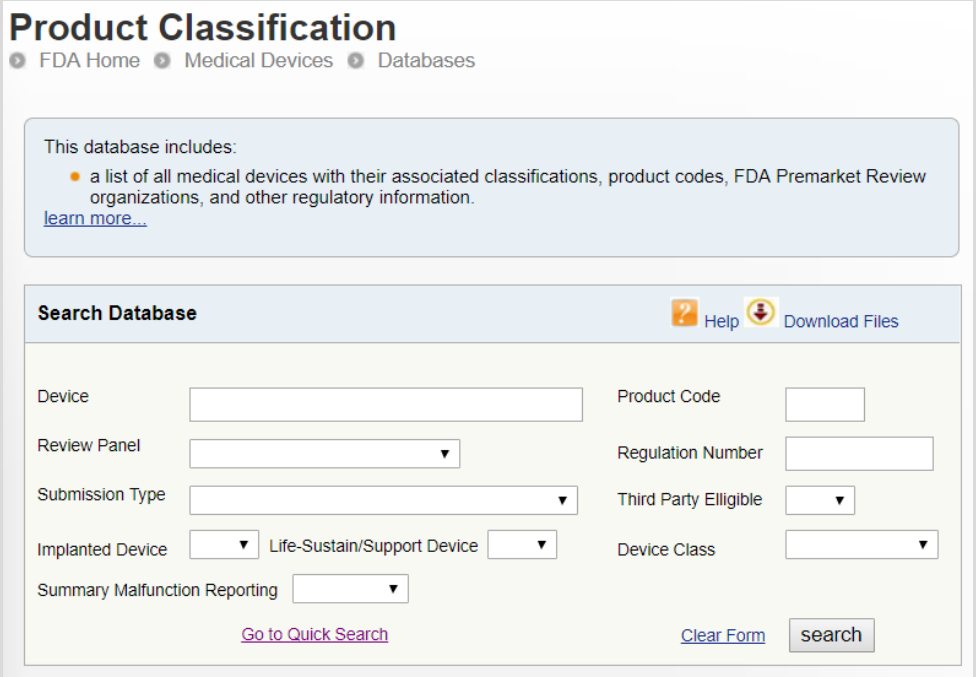
- What is the **intended use** of your product?
- How does your product **function**?
- What **claims** do you intend to make?

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 Database:
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/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**

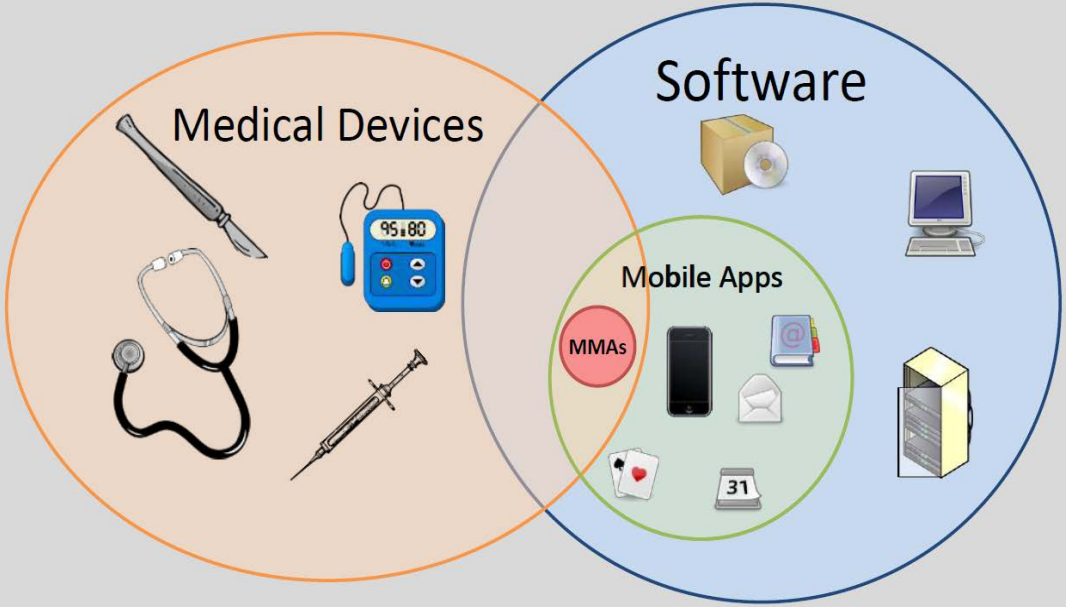
- Examples: Home Pregnancy Test, Glucose Test Strip

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

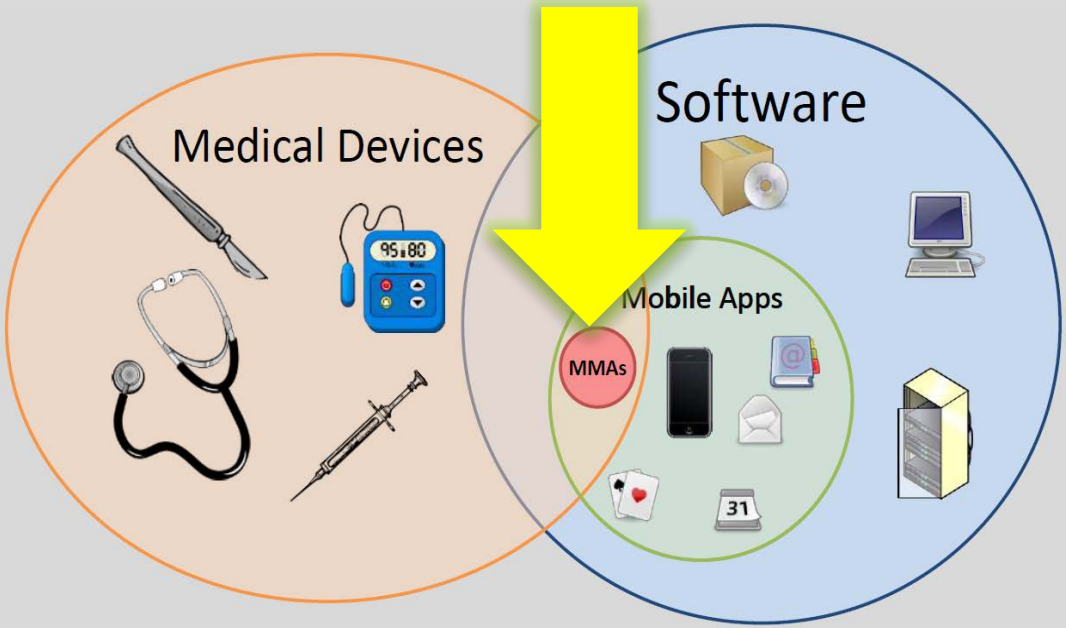
- Examples: Diagnostic Ultrasound, X-Rays, Medical Lasers

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**

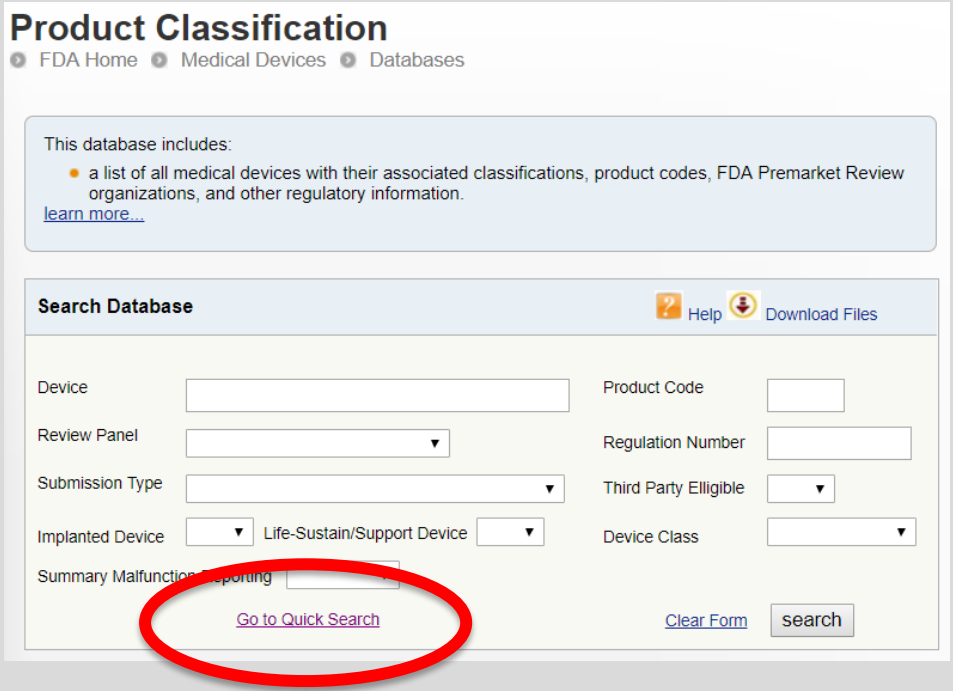
Is there an existing product classification?

Adult Diaper

VS.

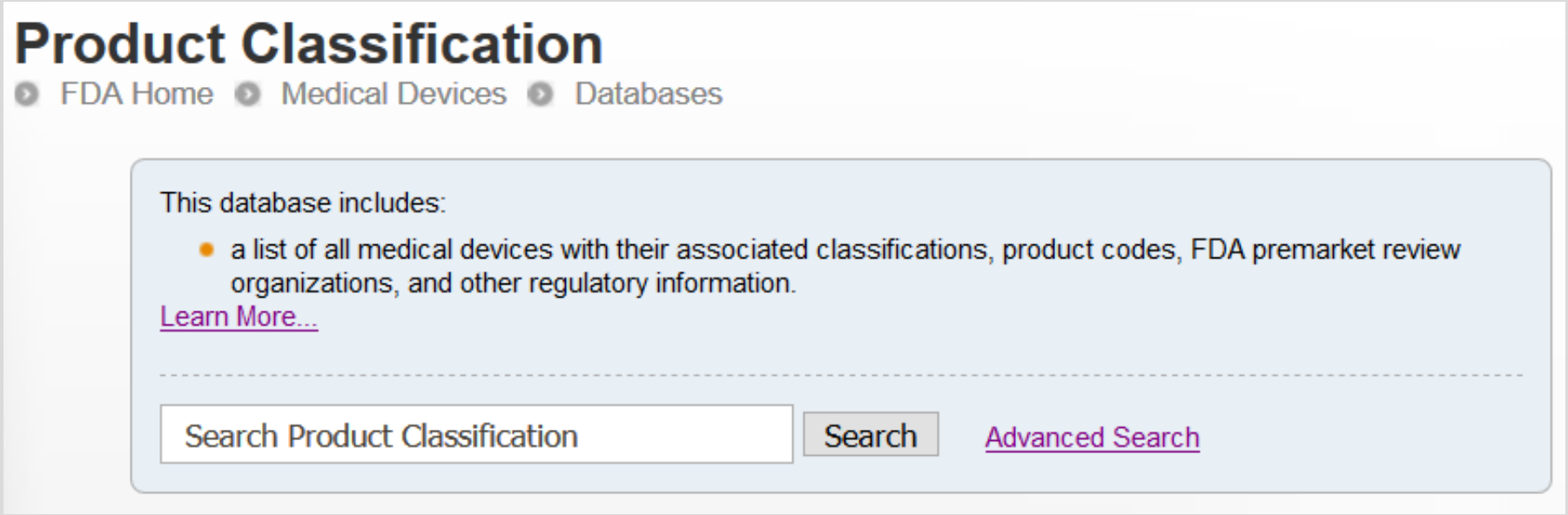
Infant Diaper

Search the Product Classification Database



Product Classification Database;
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm

Quick Search



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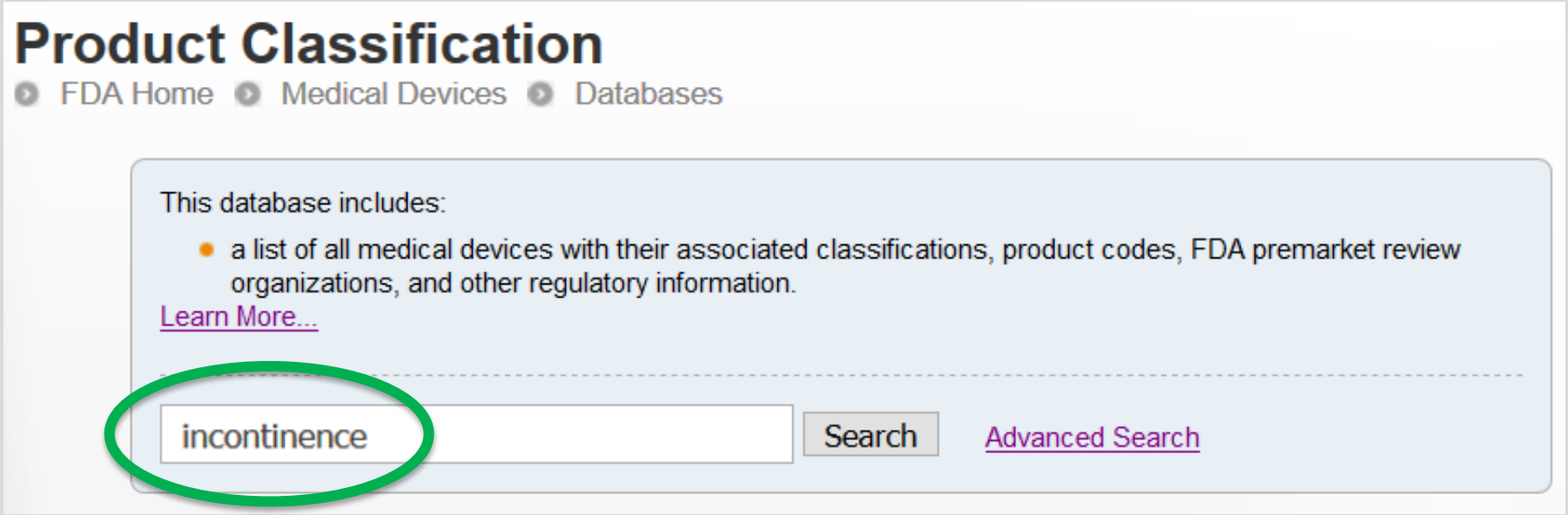
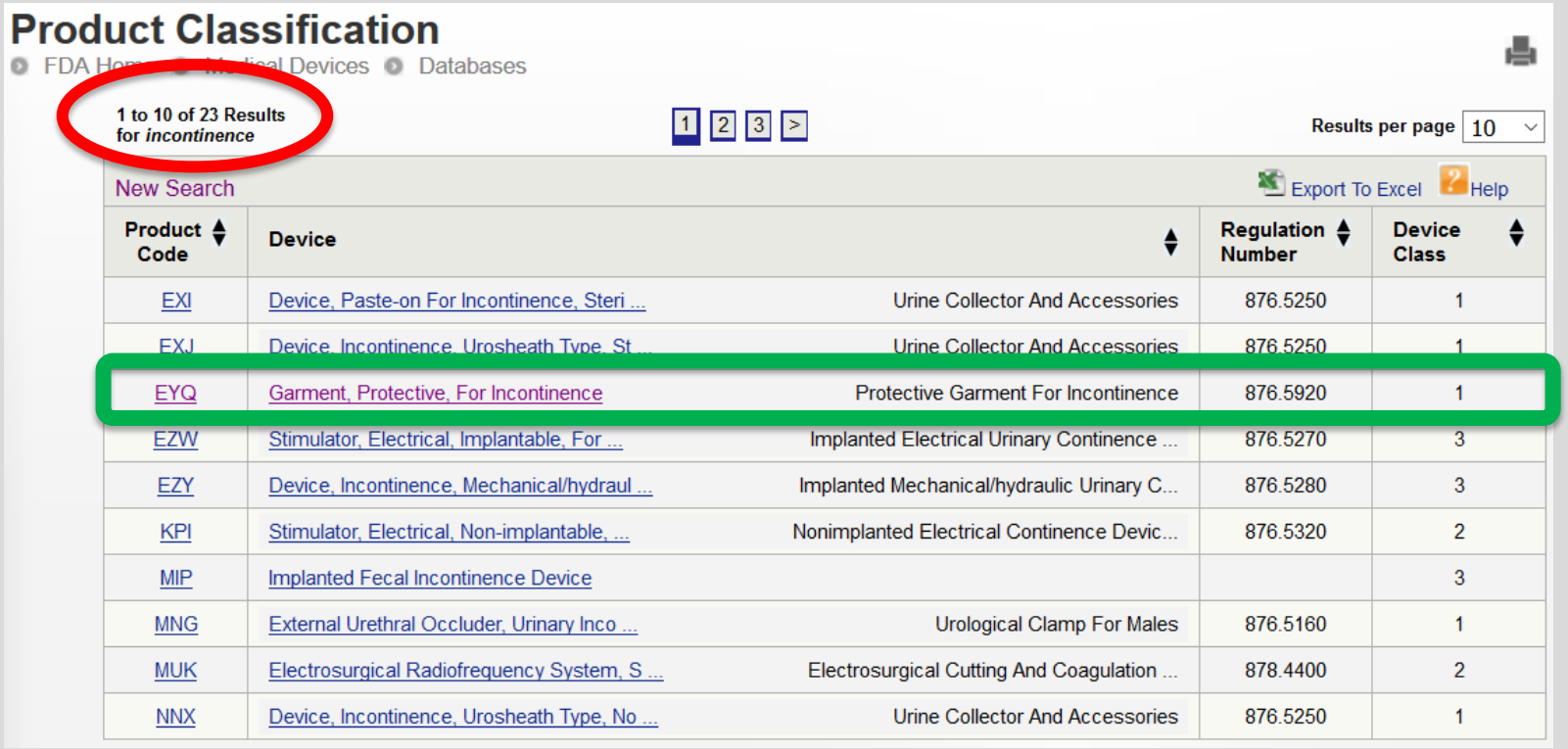


Quick Search Results



Product Classification

FDA Home › Medical Devices › Databases

1 to 10 of 23 Results for *incontinence*

1 2 3 >

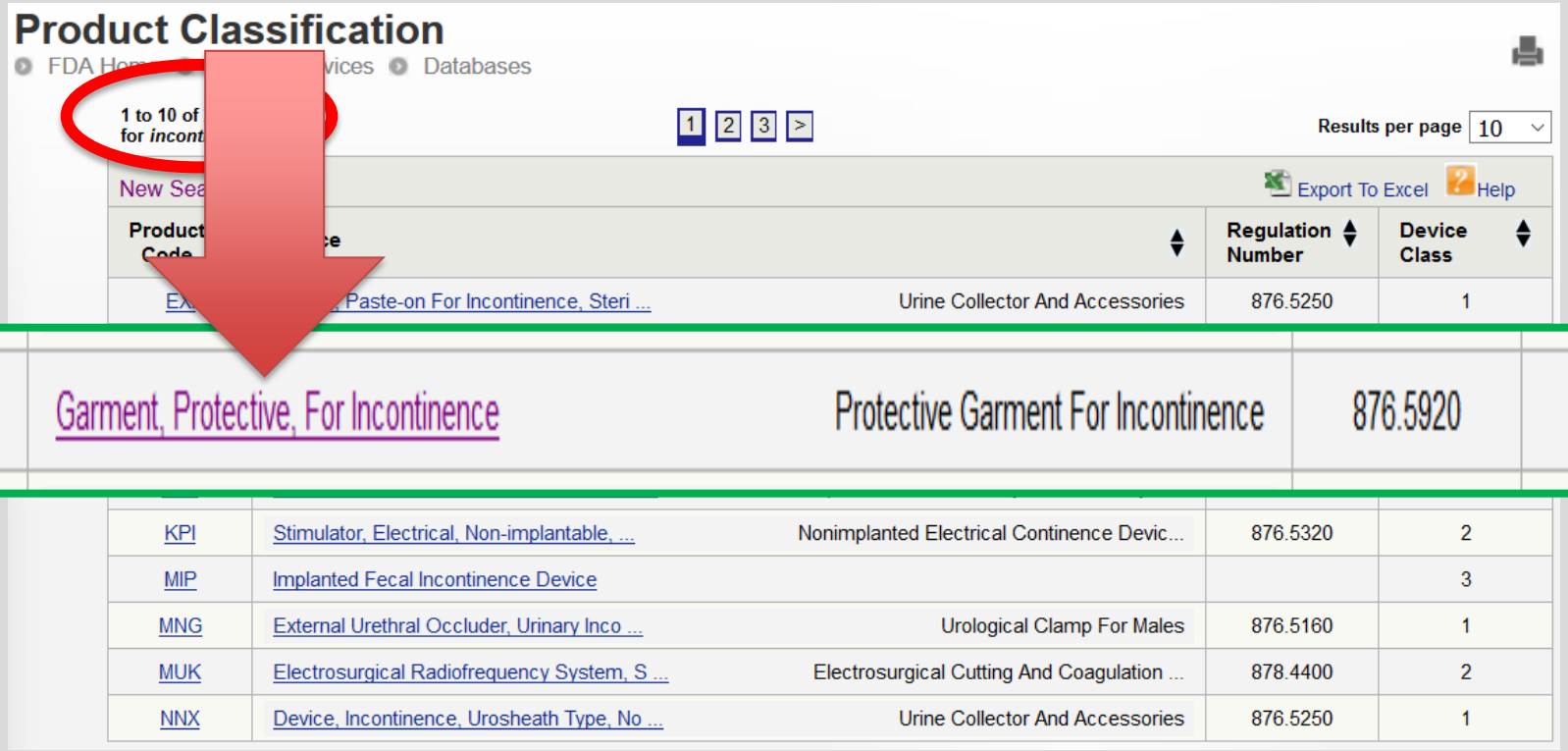
Results per page 10

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 Continence ...	876.5270	3
EZY	Device, Incontinence, Mechanical/hydraul ...	Implanted Mechanical/hydraulic Urinary C...	876.5280	3
KPI	Stimulator, Electrical, Non-implantable, ...	Nonimplanted Electrical Continence Devic...	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 "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 not labeled or otherwise represented as sterile.*

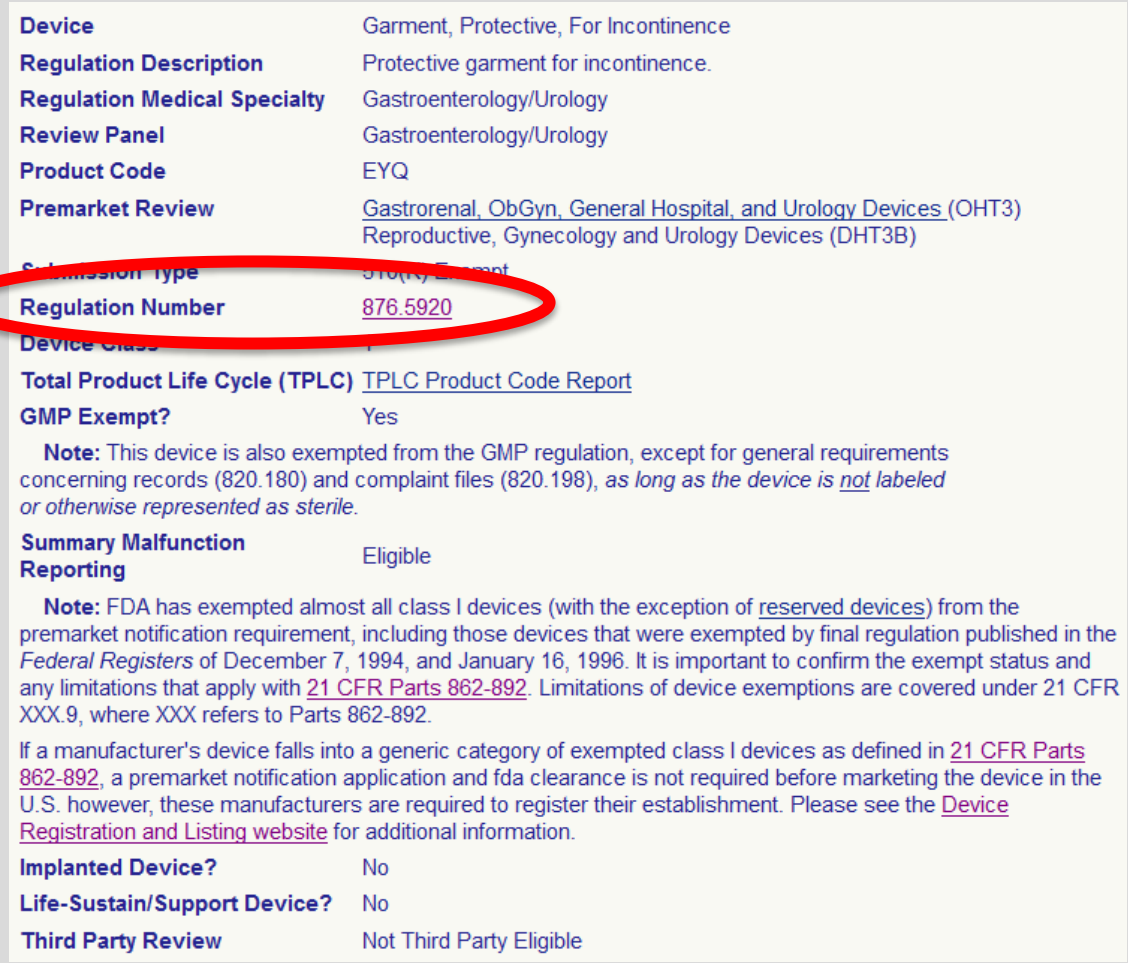
Summary Malfunction Reporting	Eligible

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 *Federal Registers* 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"



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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"

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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/cfpcd/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


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ADMINISTRATION