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 Database:
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpced/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:

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

**Infant Diaper**

Intended to protect an infant’s garments from urine or stool.
<table>
<thead>
<tr>
<th>Medical Device Definition Questions</th>
<th>Adult Diaper</th>
<th>Infant Diaper</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Is it intended to <strong>diagnose, cure, mitigate, treat, or prevent disease</strong> in a human?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>2</strong> Is it intended to <strong>affect the structure or any function of the body</strong>?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3</strong> Does it achieve its primary intended purpose by <strong>chemical action</strong> or by being <strong>metabolized</strong>?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Device Definition Questions</td>
<td>Adult Diaper</td>
<td>Infant Diaper</td>
</tr>
<tr>
<td>------------------------------------</td>
<td>-------------</td>
<td>--------------</td>
</tr>
<tr>
<td>1 Is it intended to diagnose, cure, mitigate, treat, or prevent disease in a human?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>2 Is it intended to affect the structure or any function of the body?</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>3 Does it achieve its primary intended purpose by chemical action or by being metabolized?</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Medical Device Definition Questions</td>
<td>Adult Diaper</td>
<td>Infant Diaper</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------------------------</td>
<td>--------------</td>
<td>---------------</td>
</tr>
<tr>
<td>1. Is it intended to diagnose, cure, mitigate, treat, or prevent disease in a human?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>2. Is it intended to affect the structure or any function of the body?</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>3. Does it achieve its primary intended purpose by chemical action or by being metabolized?</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Does it meet the definition of a medical device?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
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

Product Classification

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

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 input for 'incontinence']
Quick Search Results

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Device</th>
<th>Regulation Number</th>
<th>Device Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXI</td>
<td>Device, Paste-on For Incontinence, Steri...</td>
<td>876.6250</td>
<td>1</td>
</tr>
<tr>
<td>EXI</td>
<td>Device, Incontinence, Urosheath Type, St</td>
<td>876.6250</td>
<td>1</td>
</tr>
<tr>
<td>EYQ</td>
<td>Garment, Protective, For Incontinence</td>
<td>876.5820</td>
<td>1</td>
</tr>
<tr>
<td>EZW</td>
<td>Stimulator, Electrical, Implantable, For ...</td>
<td>876.5270</td>
<td>3</td>
</tr>
<tr>
<td>EZY</td>
<td>Device, Incontinence, Mechanical/hydraul...</td>
<td>876.5280</td>
<td>3</td>
</tr>
<tr>
<td>KPI</td>
<td>Stimulator, Electrical, Non-implantable, ...</td>
<td>876.5320</td>
<td>2</td>
</tr>
<tr>
<td>MIP</td>
<td>Implanted Fecal Incontinence Device</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>MNG</td>
<td>External Urethral Occluder, Urinary Inco ...</td>
<td>876.5160</td>
<td>1</td>
</tr>
<tr>
<td>MUK</td>
<td>Electrosurgical Radiofrequency System, S ...</td>
<td>876.4400</td>
<td>2</td>
</tr>
<tr>
<td>NNK</td>
<td>Device, Incontinence, Urosheath Type, No ...</td>
<td>876.6250</td>
<td>1</td>
</tr>
</tbody>
</table>
## Quick Search Results

### Product Classification

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Product Description</th>
<th>Device Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>EYQ</td>
<td>Garment, Protective, For Incontinence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Protective Garment For Incontinence</td>
<td>876.5920</td>
</tr>
</tbody>
</table>

- **KPI**: Stimulator, Electrical, Non-implantable, ...
- **MIP**: Implanted Fecal Incontinence Device
- **MNG**: External Urethral Occluder, Urinary Inco ...
- **MUK**: Electrosurgical Radiofrequency System, S ...
- **NNX**: Device, Incontinence, Urosheath Type, No ...
### Product Classification

**“Garment, Protective, For Incontinence”**

<table>
<thead>
<tr>
<th>Device</th>
<th>Garment, Protective, For Incontinence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation Description</td>
<td>Protective garment for incontinence.</td>
</tr>
<tr>
<td>Regulation Medical Specialty</td>
<td>Gastroenterology/Urology</td>
</tr>
<tr>
<td>Review Panel</td>
<td>Gastroenterology/Urology</td>
</tr>
<tr>
<td>Product Code</td>
<td>EYQ</td>
</tr>
<tr>
<td>Premarket Review</td>
<td>Gastrorenal, ObGyn, General Hospital, and Urology Devices (CHT3) Reproductive, Gynecology and Urology Devices (DHT3B)</td>
</tr>
<tr>
<td>Submission Type</td>
<td>510(K) Exempt</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>876.5920</td>
</tr>
<tr>
<td>Device Class</td>
<td>1</td>
</tr>
<tr>
<td>Total Product Life Cycle (TPLC)</td>
<td>TPLC Product Code Report</td>
</tr>
<tr>
<td>GMP Exempt?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Note:** This device is also exempted from the GMP regulation, except for general requirements concerning records (820.180) and complaint files (820.190), as long as the device is not labeled or otherwise represented as sterile.

<table>
<thead>
<tr>
<th>Summary Malfunction Reporting</th>
<th>Eligible</th>
</tr>
</thead>
</table>

**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, 1998. It is important to confirm the exempt status and any limitations that apply with [21 CFR Parts 862-892](https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&小编=ts&title=21&section=862-892& pillows=). 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](https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&小编=ts&title=21&section=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](https://www.fda.gov) for additional information.

<table>
<thead>
<tr>
<th>Implanted Device?</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life-Sustain/Support Device?</td>
<td>No</td>
</tr>
<tr>
<td>Third Party Review</td>
<td>Not Third Party Eligible</td>
</tr>
</tbody>
</table>
Product Classification
“Garment, Protective, For Incontinence”
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.

(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.
<table>
<thead>
<tr>
<th>Questions</th>
<th>Adult Diaper</th>
<th>Infant Diaper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there an existing product classification?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Is the product regulated as a medical device?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
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
  

» **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
<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Cited Resource</th>
<th>URL</th>
</tr>
</thead>
</table>
## Resources

<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Cited Resource</th>
<th>URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>Software as a Medical Device (SaMD)</td>
<td><a href="www.fda.gov/medical-devices/digital-health/software-medical-device-samd">www.fda.gov/medical-devices/digital-health/software-medical-device-samd</a></td>
</tr>
</tbody>
</table>
## Resources

<table>
<thead>
<tr>
<th>Slide Number</th>
<th>Cited Resource</th>
<th>URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>Combination Products</td>
<td><a href="http://www.fda.gov/combination-products">www.fda.gov/combination-products</a></td>
</tr>
</tbody>
</table>
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)
Familiarize yourself with:

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