U.S. FOOD & DRUG ADMINISTRATION

# Medical Device Regulatory Framework: Where to Start?

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

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START

# Learning Objectives

- Define medical device
- Describe regulatory controls
- Demonstrate the use of databases for product code/classification determination
- Identify premarket pathways

# Is My Product a Medical Device?

# Medical Device Definition

1. Is an article, an item, such as, not limited to:

- Instrument
- Machine
- Implement
- Implant
- Apparatus
- In vitro reagent

# Medical Device Definition

2. Intended for use:
   - in diagnosis of disease or other conditions
   - or in the cure, mitigation, treatment, or prevention of disease
   - or intended to affect the structure or any function of the body

# Medical Device Definition

3. Does NOT achieve its primary intended purposes through chemical action or dependent on being metabolized

- Note: Software can be a medical device
  - Certain software functions are excluded pursuant to Section 520(o) of Federal Food, Drug and Cosmetic Act

# “Intended Use” and “Indications for Use”

| Intended Use | Indications for use |
| --- | --- |
| • General purpose of device or its function.<br>• Per device label<br>• Includes indications for use. | • Describes **disease or condition** the device will diagnose, treat, prevent, cure or mitigate<br>• Includes description of **patient population** for which device is intended. |
| • **What** the device is used for | • **Where, when, and how** the device will be used |

**Determination of Intended Use for 510(k) Devices - Guidance for CDRH Staff (Update to K98-1)**

*www.fda.gov/regulatory-information/search-fda-guidance-documents/determination-intended-use-510k-devices-guidance-cdrh-staff-update-k98-1*

# Medical Device Definition

**KNOWLEDGE AT YOUR FINGERTIPS**

- 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?

# Knowledge Check

**Which of the below item(s) is a medical device? Select all that apply.**

# Regulatory Controls

# Regulatory Controls

- Ensure safety and effectiveness of medical devices
- Provide consistent requirements
- Based on the level of risk
- General, Special and PMA controls

# Examples of General Controls

| Control | Regulation (21 CFR Part) | Brief Description |
|---|---|---|
| Labeling | 801 | provide information for users |
| Medical Device Reporting | 803 | report device-related injuries and deaths |
| Establishment Registration | 807 | register business with FDA |
| Device Listing | 807 | identify devices |
| Quality System | 820 | ensure safe, effective finished devices |
| Adulteration | FD&C Act 501 | contaminated, filthy, putrid, or decomposed substances or intention of committing fraud |
| Misbranding | FD&C Act 502 | provide false or misleading labeling |

# Special Controls

- Apply when general controls are insufficient
- Examples
  - Special labeling requirements
  - Mandatory performance standards
  - Postmarket surveillance
  - Premarket data requirements
  - Patient registries

# PMA Controls

- Along with general controls
- Typically for life supporting or life sustaining devices (Class III)
- 21 CFR 814

# Regulatory Controls

**KNOWLEDGE AT YOUR FINGERTIPS**

- Regulatory Controls
- Class II Special Controls Documents | FDA
- CDRH Learn: An Introduction to FDA's Regulation of Devices

# Knowledge Check

**My device is classified as Class II, but is 510(k) exempt. Exempt means no regulatory controls apply to my device.**

A. True

B. False

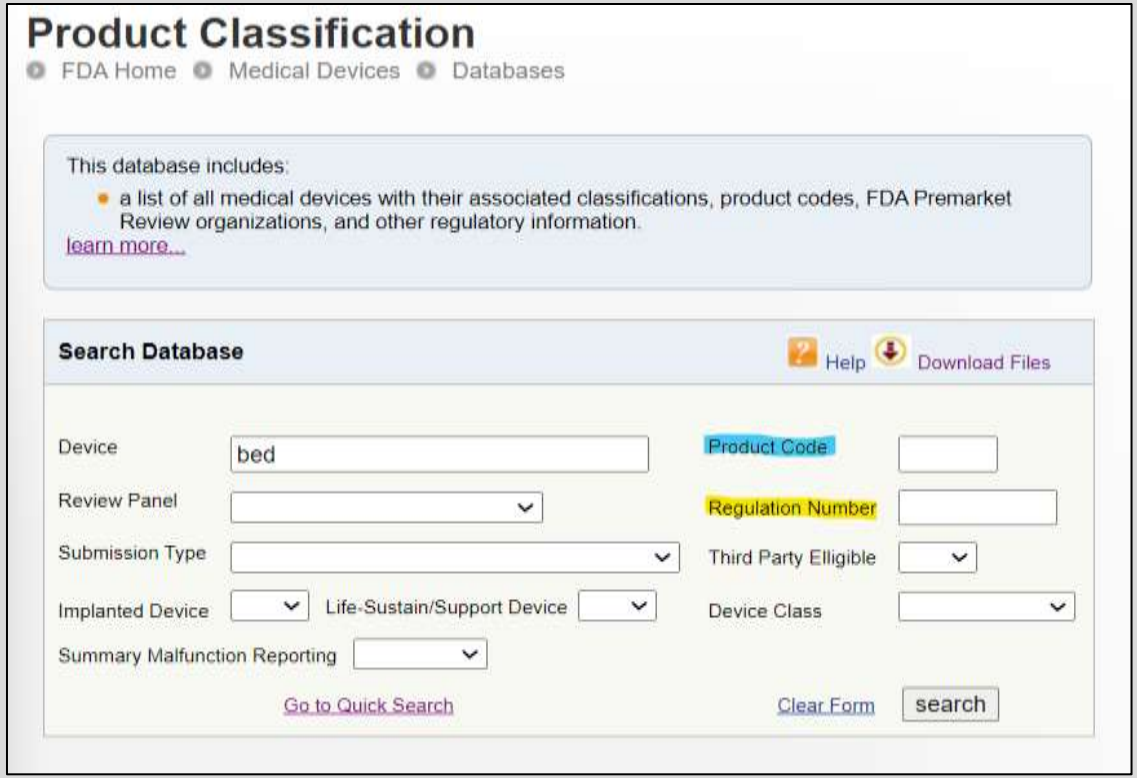
# SEARCHING DATABASES

# Product Classification Codes

- Three letter codes (example: OBN, FMA)
- Used by the FDA to identify and track similar medical device
- Provides applicable CFR regulation
- Provides marketing pathway

# How to Find Product Classification Code

[Product Classification](#) find existing classification that describes your medical device



# Search Results for “Bed”

## Product Classification

FDA Ho... Devices Databases

1 to 10 of 25 results
*bed*

1 2 3 >

Results per page 10

New Search

Export to Excel Help

| Product Code | Device | | Regulation Number | Device Class |
|---|---|---|---|---|
| CCO | Bed, Rocking, Breathing Assist | Rocking Bed | 868.5180 | 2 |
| FMS | Bed, Pediatric Open Hospital | Pediatric Medical Crib | 880.5140 | 2 |
| FNL | Bed, Ac-Powered Adjustable Hospital | AC-Powered Adjustable Hospital Bed | 880.5100 | 2 |
| LLI | Bed, Therapeutic, Ac-Powered, Adjustable Home-Use | AC-Powered Adjustable Hospital Bed | 880.5100 | 2 |
| OSI | Bariatric Bed | AC-Powered Adjustable Hospital Bed | 880.5100 | 2 |
| IKZ | Bed, Patient Rotation, Powered | Powered Patient Rotation Bed | 890.5225 | 2 |
| INX | Bed, Air Fluidized | Air-Fluidized Bed | 890.5160 | 2 |
| IOQ | Bed, Flotation Therapy, Powered | Powered Flotation Therapy Bed | 890.5170 | 2 |
| MOC | Cushion, Flotation, Therapeutic | Powered Flotation Therapy Bed | 890.5170 | 2 |
| REF | Suntan Bed | Sunlamp Products And Ultraviolet Lamps I... | 878.4635 | 2 |

New Search

Help | More About 21CFR

[Code of Federal Regulations]
[Title 21, Volume 8]
[CITE: 21CFR890.5160]

See Related Information

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

PART 890 -- PHYSICAL MEDICINE DEVICES

Subpart F - Physical Medicine Therapeutic Devices

Sec. 890.5160 Air-fluidized bed.

(a) *Identification*. An air-fluidized bed is a device employing the circulation of filtered air through ceramic spherules (small, round ceramic objects) that is intended for medical purposes to treat or prevent bedsores, to treat severe or extensive burns, or to aid circulation.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59231, Nov. 3, 1998]

# Regulation for Air-fluidized bed

# Search Results for “Bed”

## Product Classification

FDA Home › Medical Devices › Databases

1 to 10 of 25 results
*bed*

1 2 3 >

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| OSI | Bariatric Bed | AC-Powered Adjustable Hospital Bed | 880.5100 | 2 |
| IKZ | Bed, Patient Rotation, Powered | Powered Patient Rotation Bed | 890.5225 | 2 |
| INX | Bed, Air Fluidized | Air-Fluidized Bed | 890.5160 | 2 |
| IOQ | Bed, Flotation Therapy, Powered | Powered Flotation Therapy Bed | 890.5170 | 2 |
| MOC | Cushion, Flotation, Therapeutic | Powered Flotation Therapy Bed | 890.5170 | 2 |
| REF | Suntan Bed | Sunlamp Products And Ultraviolet Lamps I... | 878.4635 | 2 |

# Product Classification for Air-Fluidized Bed

New Search | Back to Search Results

| | |
|---|---|
| **Device** | Bed, Air Fluidized |
| **Regulation Medical Specialty** | Physical Medicine |
| **Review Panel** | Physical Medicine |
| **Product Code** | INX |
| **Premarket Review** | Neuromodulation and Physical Medicine Devices (DHT5B)<br>Neuromodulation and Physical Medicine Devices (DHT5B) |
| **Submission Type** | 510(K) Exempt |
| **Regulation Number** | 890.5160 |
| **Device Class** | 2 |
| **Total Product Life Cycle (TPLC)** | TPLC Product Code Report |
| **GMP Exempt?** | No |
| **Summary Malfunction Reporting** | Eligible |

**Note: Class II devices** the Food and Drug Administration (FDA) has also published a list of class II (special controls) devices subject to certain limitations, that are exempt from premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (FDAMA) and the 21st Century Cures Act of 2016 (Cures Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet requirements of FDAMA and the Cures Act.

| | |
|---|---|
| **Implanted Device?** | No |
| **Life-Sustain/Support Device?** | No |
| **Third Party Review** | Not Third Party Eligible |

# Additional Databases

**KNOWLEDGE AT YOUR FINGERTIPS**

Establishment Registration & Device Listing

CFR - Code of Federal Regulations Title 21

Medical Device Databases | FDA

# Premarket Pathways

# 510(K)

- Exempt
  - Class I or II devices
  - General controls, unless regulation states otherwise
- Required (not exempt)
  - Class I or II devices
  - Demonstrate the device is substantially equivalent to a predicate device

# De Novo

- Novel devices; No predicate device exists
  - Automatic Class III devices
- Risk-based classification process
- Results in reclassification to Class I or Class II
- General controls or general and special controls

# Premarket Approval (PMA)

- Class III devices
- General and PMA controls
- Provide valid scientific evidence to assure safety and effectiveness for intended use

# Humanitarian Device Exemption (HDE)

- No comparable device currently legally marketed in United States to treat or diagnose the disease or condition
- Requires Humanitarian Use Device (HUD) designation first
  - For rare diseases and conditions
  - Affects or manifests in not more than 8,000 people in US per year
- Demonstrates no significant risk and probable benefit

# Organizing All the Possibilities

| Class | Potential Harm | Controls | Submission Type(s) | Percent Devices in Class |
|---|---|---|---|---|
| I | Present minimal potential for harm | General | 510(k) Exempt<br>510(k)<br>De Novo (very few)<br><br>* 93% are exempt from 510(k) submission | 35% |
| II | Higher risk than Class I devices | General and Special | 510(k) Exempt<br>510(k)<br>De Novo (few) | 53% |
| III | Sustain or support life, are implanted, or present potential unreasonable risk of illness or injury | General and PMA | PMA | 9% |

# Premarket Pathway

**KNOWLEDGE AT YOUR FINGERTIPS**

- How to Study and Market Your Device | FDA
- Classify Your Medical Device
- CDRH Learn – Device Classification

# Resources

| Slide Number | Cited Resource | URL |
|---|---|---|
| 9 | 21 U.S.C. 321(h) | uscode.house.gov/view.xhtml?req=(title:21%20section:321%20edition:prelim)%20OR%20(granuleid:USC-prelim-title21-section321)&f=treesort&edition=prelim&num=0&jumpTo=true |
| 9 | Device Advice: How to Determine if Your Product is a Medical Device | www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device |
| 9 | CDRH Learn Module: Is My Product a Medical Device | fda.yorkcast.com/webcast/Play/e0eec5f6ee3d4947a70fcedef32993f71d |
| 15 | 21 CFR 814 | www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=814 |
| 16 | Device Advice: Regulatory Controls | www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls |

# Resources

| Slide Number | Cited Resource | URL |
|---|---|---|
| 16 | Class II Special Controls Document | www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/class-ii-special-controls-documents |
| 16 | CDRH Learn – An Introduction to FDA's Regulation of Devices | fda.yorkcast.com/webcast/Play/884aea9662174dea8ef4df68988b86981d |
| 21 | Database: Product Classification | www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm |
| 26 | Database: Establishment Registration & Device Listing | www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm |
| 26 | CFR – Code of Federal Regulations Title 21 | www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm |

# Resources

| Slide Number | Cited Resource | URL |
|---|---|---|
| 26 | Medical Device Databases | www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases |
| 33 | Device Advice: How to Study and Market Your Device | www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device |
| 33 | Device Advice: Classify Your Medical Device | www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device |
| 33 | CDRH Learn: Device Classification | fda.yorkcast.com/webcast/Play/17792840509f49f0875806b6e9a1be471d |

# Summary

- Ensure product meets definition of medical device
- Regulatory controls increase with device risk
- Public databases can assist with product code and classification determination
- Knowing product classification code and regulation for the device will facilitate appropriate selection of premarket pathway

# Questions