

Medical Device Regulatory Framework: Where to Start?

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A scenic landscape featuring a paved road that curves through a lush green area with many trees. A faint rainbow is visible in the sky above the trees. The word "START" is written in large, white, italicized letters across the bottom of the road.

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
<ul style="list-style-type: none">• General purpose of device or its function.• Per device label• Includes indications for use.• What the device is used for	<ul style="list-style-type: none">• Describes disease or condition the device will diagnose, treat, prevent, cure or mitigate• Includes description of patient population for which device is intended.• Where, when, and how the device will be used

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
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- [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

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](#)
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Device	<input type="text" value="bed"/>	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"/>
Summary Malfunction Reporting	<input type="text"/>	Device Class	<input type="text"/>

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

Search Results for “Bed”



Product Classification

FDA Home Medical Devices Databases

1 to 10 of 25 results
bed

1 2 3 >

Results per page 10

[New Search](#)

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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]



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](#)



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bed

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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) Neuromodulation and Physical Medicine Devices (DHT5B)
Submission Type	510(K) Exempt
Regulation Number	890.5160
Device Class	2
Total Product Life Cycle (TCLC)	TCLC Product Code Report
GMP Exempt?	No
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



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[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 510(k) De Novo (very few) * 93% are exempt from 510(k) submission	35%
II	Higher risk than Class I devices	General and Special	510(k) Exempt 510(k) 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
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- [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/cfpd/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

