

FDA and Medical Devices

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Today's Roadmap

- An overview of the Food and Drug Administration
- Manufacturer/establishment registration and medical device listing
- Premarket notification 510(k) clearance and premarket approval
- Determining Device Classifications
- Investigational Device Exemption (IDE) for clinical studies
- Quality system regulation and labeling requirements
- Medical device and adverse event reporting

FDA Overview

- **The Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services.**
 - **It consists of the Office of the Commissioner and four directorates overseeing the core functions of the agency:**
 - **Medical Products and Tobacco;**
 - **Food and Veterinary Medicine;**
 - **Global Regulatory Operations and Policy; and**
 - **Operations.**

FDA Responsibility

- **FDA is responsible for:**
 - **Protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices;**
 - **Protecting the public health by assuring that food (except for meat from livestock, poultry and some egg products which are regulated by the Department of Agriculture) are safe, wholesome, sanitary and properly labeled;**

FDA Responsibility (continued)

- Protecting the public from electronic product radiation;
 - Assuring cosmetics and dietary supplements are safe and properly labeled;
 - Regulating tobacco products; and
 - Advancing the public health by helping to speed product innovations.
- FDA's responsibilities extend to all 50 states, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, and other U.S. territories and possessions.

FDA Responsibility for Food

- **FDA regulates foods, including:**
 - dietary supplements
 - bottled water
 - food additives
 - infant formulas and
 - other food products (although the USDA plays the lead role in regulating aspects of some meat, poultry, and egg products).

FDA Responsibility for Cosmetics

- **FDA regulates cosmetics, including:**
 - **color additives found in makeup and other personal care products**
 - **skin moisturizers and cleansers**
 - **nail polish and perfume.**

FDA Responsibility for Electronic Products that Give Off Radiation

- FDA regulates electronic products that give off radiation, including:
 - microwave ovens
 - x-ray equipment
 - laser products
 - ultrasonic therapy equipment
 - mercury vapor lamps
 - sunlamps

FDA Responsibility for Veterinary Products

- FDA regulates veterinary products, including:
 - livestock feeds
 - pet foods
 - veterinary drugs and devices

FDA Responsibility for Drugs

- **FDA regulates drugs and biologics, including:**
 - prescription drugs (both brand-name and generic)
 - non-prescription (over-the-counter) drugs
 - vaccines
 - blood and blood products
 - cellular and gene therapy products
 - tissue and tissue products
 - allergenics

FDA Responsibility for Tobacco Products

- **FDA regulates tobacco products, including:**
 - Cigarettes
 - Cigarette tobacco
 - Roll-your-own tobacco
 - Smokeless tobacco
 - electronic nicotine delivery products (ENDS) including e-cigarettes, vaporizers, vape pens, hookah pens
- **This includes the manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of tobacco products.**

FDA Responsibility for Medical Devices

- **FDA regulates medical devices, including:**
 - simple items like tongue depressors and bedpans
 - complex technologies such as heart pacemakers
 - dental devices
 - surgical implants and prosthetics
 - devices used to diagnosis disease or injury
 - devices intended to treat illness or injury
 - just about any device used by medical providers in a hospital, post-acute care facility, or clinical setting.

FDA Resources

- For FY 2013, FDA employed 14,648 FTEs
 - The Center for Devices and Radiological Health employed 1,413 full-time staff
 - By comparison, the Center for Drug Evaluation and Research employed 3,603
 - The Center for Food Safety and Applied Nutrition employed 1,082
 - The Center for Biologics Evaluation and Research employed 1,074
 - The Office of Regulatory Affairs employed 5,068.

Federal Law and FDA Guidance

- The Federal Food, Drug, and Cosmetic Act (the “Act”) is a federal law enacted by Congress. [\(21 U.S.C. 301\)](#).
- The Act and other federal laws establish the legal framework with which the FDA operates.
 - FDA develops regulations following the procedures required by the Administrative Procedure Act
 - Typically by "notice and comment rulemaking" that allows the public to provide input on a proposed regulation before FDA issues a final rule.
- FDA also follows procedures required by its "Good Guidance Practice" [\(21 CFR 10.115\)](#) in issuing guidance.
 - Guidance is not legally binding on the public or FDA.
 - FDA guidance describes the agency's current thinking on a regulatory issue.

Overlapping and Other Key Agencies

- Federal Trade Commission (FTC) regulates many types of advertising.
- Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau regulates aspects of alcohol production, importation, wholesale, distribution, labeling, and advertising.
- Consumer Product Safety Commission (CPSC) regulates the safety of consumer products such as toys, cribs, power tools, cigarette lighters, household chemicals, and other products that pose a fire, electrical, chemical or mechanical hazard.
- The US Department of Agriculture's Food Safety and Inspection Service regulates aspects of the safety in labeling of traditional (non-game) meats, poultry, and certain egg products.
- Environmental Protection Agency (EPA) regulates pesticides and the type and amounts that can be used during growing and how much can remain in foods.

Office of Medical Products and Tobacco Organization

- **Organized into the following subdivisions:**
 - **Center for Drug Evaluation and Research**
 - **Center for Biologics Evaluation and Research**
 - **Center for Devices and Radiological Health**
 - **Center for Tobacco Products**
 - **Office of Special Medical Programs**
 - **Office of Combination Products**
 - **Office of Good Clinical Practice**
 - **Office of Pediatric Therapeutics**
 - **Office of Orphan Products Development**

Center for Devices and Radiological Health (CDRH)

- The Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting public health.
- Tasked with providing consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products FDA oversees.
- Duty to facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

CDRH – Establishment Registration

- CDHR regulation extends to firms who manufacture, repackage, relabel, and/or import medical devices sold in the U.S.
- Manufacturers (both domestic and foreign) and initial distributors (importers) of medical devices must register their establishments with the FDA.
 - Establishment registrations must be submitted electronically unless a waiver has been granted.
 - Registration information must be verified annually between October 1st and December 31st of each year.
 - Foreign manufacturers must also designate a U.S. Agent.
 - There is an annual registration fee (which is not eligible for a reduced small business fee).
 - For FY 2016, the annual registration fee was \$3,845
 - The estimated annual registration user fee for FY 2017 is \$3,872 (the actual fee will be determined and posted by August 2016)
 - “Who Must Register, List and Pay the Fee”
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm>

Device Registration and Listing

- In addition to requiring establishments to register, manufacturers must also list their devices with the FDA and the activities that are performed on those devices.
- Establishments required to list their devices include:
 - manufacturers
 - contract manufacturers that commercially distribute the device
 - contract sterilizers that commercially distribute the device
 - repackagers and relabelers
 - specification developers
 - reproprocessors of single-use devices
 - remanufacturers
 - manufacturers of accessories and components sold directly to the end user
 - U.S. manufacturers of "export only" devices

Medical Device Classifications

- For FDA purposes, medical devices are categorized into three regulatory classes.
- The device classification determines the regulatory requirements for a general device type.
 - Class I medical devices are those that present the lowest risk of causing harm (i.e., tongue depressors) and, correspondingly are subject to the lowest degree of FDA regulation.
 - Most Class I devices are **exempt** from Premarket Notification 510(k).
 - Class II devices have some potential for harm and typically require Premarket Notification 510(k).
 - However, some Class II devices are also **exempt** from Premarket Notification 510(k).
 - Class III devices present significant risk and most require Premarket Approval (PMA).

FDA Clearance

- Each entity/individual who wants to market in the U.S. a Class I, II, or III device intended for human use, and for which a Premarket Approval (PMA) is not required, must submit a 510(k) to the FDA unless the device is exempt from 510(k) requirements.
- There is no 510(k) form but [21 CFR 807 Subpart E](#) describes requirements for a 510(k) submission.
- Before marketing a device, each applicant must receive an order, in the form of a letter, from FDA which finds a device to be substantially equivalent (SE) and states the device can be marketed in the U.S.
- This order "clears" the device for commercial distribution.
 - Technically speaking, the FDA does not "approve" a device; rather it grants a "clearance."

510(k) Premarket Submissions

- A 510(k) is a premarket submissions made to FDA to demonstrate that the device to be marketed is at least as safe and effective (substantially equivalent) to a legally marketed device that is not subject to PMA. [21 CFR 807.92 \(a\) \(3\)](#)
- Submitters must compare their device to one or more similar legally marketed devices (“predicate device”) and make and support their substantial equivalency claims.

510(k) Premarket Submissions

- A legally marketed device, (as described in [21 CFR 807.92\(a\)\(3\)](#)), is a device:
 - that was legally marketed prior to May 28, 1976 (preamendments device) for which a PMA is not required; or
 - a device which has been reclassified from Class III to Class II or I;
 - or a device which has been found substantially equivalent through the 510(k) process.
- Until the applicant receives an order declaring the device substantially equivalent, the device cannot be marketed in the U.S.
- Substantially equivalent determinations are usually made within 90 days (if adequate information is submitted).
- A manufacturer should be prepared for an FDA quality system ([21 CFR 820](#)) inspection at any time after 510(k) clearance.

Substantial Equivalence

- Substantial equivalence means that the new device is at least as safe and effective as the predicate.
- A device is substantially equivalent if, in comparison to a predicate it:
 - has the same intended use as the predicate and has the same technological characteristics as the predicate; or
 - has the same intended use as the predicate and has different technological characteristics and the information submitted to the FDA
 - does not raise new questions of safety and effectiveness; and
 - demonstrates that the device is at least as safe and effective as the legally marketed device

Substantial Equivalence

- Substantial equivalence does not mean the new and predicate devices must be identical.
- Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility standards, and other characteristics (as applicable).
- Again, a device may not be marketed in the U.S. until the submitter receives a letter declaring the device is substantially equivalent to a legally marketed predicate device.

Substantial Equivalence

- If the FDA determines that the device is not substantially equivalent, the applicant may:
 - resubmit another 510(k) with new data,
 - request a Class I or II designation through the de novo process,
 - file a reclassification petition, or
 - submit a premarket approval application (PMA).

Determining Who Is Required to Submit a 510(k)

- The Act and the 510(k) regulation ([21 CFR 807](#)) do not specify who must apply for a 510(k).
- Instead, these regulations specify which actions require a 510(k) submission. These include the four following categories of parties who must submit a 510(k) to the FDA:
 1. Domestic manufacturers introducing a device to the U.S. market;
 2. Specification developers introducing a device to the U.S. market;
 - A specification developer is the individual or entity that develops the specifications for a finished device, but has the device manufactured under contract by another firm or entity.
 - A specification developer submits the 510(k), not the contract manufacturer.

Determining Who Is Required to Submit a 510(k)

3. Repackagers or relabelers who make labeling changes or whose operations significantly affect the device;
 - Significant labeling changes may include modification of manuals, such as adding a new intended use, deleting or adding warnings, contraindications, etc.
 - Operations, such as sterilization, could alter the condition of the device.
 - Note that most repackagers or relabelers are not required to submit a 510(k)
4. Foreign manufacturers/exporters or U.S. representatives of foreign manufacturers/exporters introducing a device to the U.S. market.

When a 510(k) is Required

- **A 510(k) is required when:**
 1. **Introducing a device into commercial distribution for the first time.**
 - After May 28, 1976 (effective date of the Medical Device Amendments to the Act), anyone who wants to sell a device in the U.S. is required to make a 510(k) submission at least 90 days prior to offering the device for sale, even though it may have been under development or clinical investigation before that date.
 2. **The applicant is proposing a different intended use for the device which it already has an commercial distribution.**
 - Intended use is indicated by claims made for a device in labeling or advertising.
 - Almost all changes in intended use will require a 510(k).

When a 510(k) is Required

3. There is a change or modification of a legally marketed device and that change could significantly affect its safety or effectiveness.
 - The burden is on the 510(k) holder to decide whether or not a modification could significantly affect the safety or effectiveness of the device.
 - Any modifications must be made in accordance with the Quality System regulation, [21 CFR 820](#), and recorded in the device master record and change control records.
 - The best practice is to record the justification for submitting or not submitting a new 510(k) in the change control records.

When a 510(k) is Not Required

- The following are examples of when a 510(k) is not required:
 1. You sell unfinished devices to another firm for further processing or sell components to be used in the assembling of devices by other firms.
 - However, if your components are to be sold directly to end users as replacement parts, a 510(k) is required.
 2. Your device is not being marketed or commercially distributed.
 - A 510 K is not needed to develop, evaluate, or test or device, including clinical evaluation.
 - If you perform clinical trials with your device, you are subject to the Investigational Device Exemption (IDE) regulation ([21 CFR 812](#)).
 3. You distribute another firm's domestically manufactured device.
 - You may place a label on the device indicating, "Distributed by ABC Firm" or "Manufactured by ABC Firm" and sell to end users without obtaining 510(k) clearance.

When a 510(k) is Not Required

4. In most cases, if you are a repackaged or a relabeler you are not required to submit a 510(k) if the existing labeling or condition of the device is not significantly changed.
 - The labeling should be consistent with the labeling submitted in the 510(k) with the same indications for use and warnings and contraindications.
5. You have proof that your device was legally in commercial distribution before May 28, 1976 .
 - These devices are "grandfathered" and have Preamendment Status.
 - No 510(k) is necessary unless the device has been significantly modified or there has been a change in its intended use.

When a 510(k) is Not Required

6. The device is made outside the U.S. and you are an importer of the foreign-made medical device.
 - A 510(k) is not required if one has already been submitted by the foreign manufacturer and received marketing clearance.
 - Once a foreign manufacturer has received 510(k) clearance for the device, the foreign manufacturer may export its device to any U.S. importer.

When a 510(k) is Not Required

7. Your device is exempted from 510(k) by regulation (**21 CFR 862-892**).
 - Certain Class I and II devices can be marketed for the first time without having to submit a 510(K).
 - A list of the Class I and II exempted devices can be found on the Medical Device Exemptions 510(k) and GMP Requirements at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm>

Class I and II Exempt Devices

Class I and Class II Exempt Devices

PART 862	CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES
PART 864	HEMATOLOGY AND PATHOLOGY DEVICES
PART 866	IMMUNOLOGY AND MICROBIOLOGY DEVICES
PART 868	ANESTHESIOLOGY DEVICES
PART 870	CARDIOVASCULAR DEVICES
PART 872	DENTAL DEVICES
PART 874	EAR, NOSE, AND THROAT DEVICES
PART 876	GASTROENTEROLOGY-UROLOGY DEVICES
PART 878	GENERAL AND PLASTIC SURGERY DEVICES
PART 880	GENERAL HOSPITAL AND PERSONAL USE DEVICES
PART 882	NEUROLOGICAL DEVICES
PART 884	OBSTETRICAL AND GYNECOLOGICAL DEVICES
PART 886	OPHTHALMIC DEVICES
PART 888	ORTHOPEDIC DEVICES
PART 890	PHYSICAL MEDICINE DEVICES
PART 892	RADIOLOGY DEVICES

Premarket Approval (PMA)

- Products requiring PMAs are Class III devices that pose a significant risk of illness or injury, or devices found not substantially equivalent to Class I and II predicates through the 510(k) process.
- The PMA process involves scientific and regulatory review to evaluate the safety and effectiveness of the Class III medical device.
 - Safety and efficacy is typically demonstrated through clinical trials and scientifically validated research.
- Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.
- PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use.

PMA Devices

- The PMA applicant is usually the person who owns the rights, or otherwise has authorized access, to the data and other information to be submitted in support of FDA approval.
- This person may be an individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit, or other legal entity.
 - The applicant is often the inventor/developer and ultimately the manufacturer.
 - An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device.

PMA Devices

- If the device is a high risk device (supports or sustains human life, is of substantial importance in preventing impairment of human health, or presents a potential, unreasonable risk of illness or injury) and has been found to be not substantially equivalent to a Class I, II, or III (Class III requiring 510(k)) device, the device must be PMA approved before marketing in the U.S.
- Some devices that are found to be not substantially equivalent to a cleared Class I, II, or III (not requiring PMA) device, may be eligible for the de novo process as a Class I or II device.
 - Information on the de novo process can be found in FDA guidance “New Section 513(f)(2) – Evaluation of Automatic Class III Designation: Guidance for Industry and CDRH Staff at:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080195.htm>

Determining a Device's Classification

- The FDA has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as “panels.”
- There are two different ways to determine the classification of a device:
 1. using the Product Code Classification Database, or
 2. using the Device Panel Database

Product Code Classification Database

- Go to <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>
- You will see the following:

U.S. Department of Health & Human Services

U.S. Food and Drug Administration
Protecting and Promoting Your Health

A to Z Index | Follow FDA | En Español

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

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"/>

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

Other Databases

- 510(k)s
- De Novo
- Medical Device Reports (MAUDE)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Humanitarian Device Exemption
- Inspections
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Registration & Listing
- Standards
- Total Product Life Cycle
- X-Ray Assembler

Need information about classifying your device?

[Device Classification](#)

Product Code Classification Database

- **Put in your search term .**
 - For example, if you are looking for snoring cessation devices you can use the search term “snoring.”
- **Also include whether it is an implanted device and whether it is life-sustaining/support device.**
 - Using just these search terms will often take you to the controlling regulation.

Product Code Classification Database

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Ani

Product Classification

FDA Home | Medical Devices | Databases

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[Learn More..](#)

Search Database [Help](#) [Download Files](#)

Device	<input type="text" value="snoring"/>	Product Code	<input type="text"/>
Review Panel	<input type="text" value=""/>	Regulation Number	<input type="text"/>
SubmissionType	<input type="text" value=""/>	Third Party Elligible	<input type="text" value=""/>
Implanted Device	<input type="text" value="No"/> Life-Sustain/Support Device <input type="text" value="No"/>	Device Class	<input type="text" value=""/>

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

- This search will result in the following information:

Product Code Classification Database

Product Classification

[FDA Home](#) [Medical Devices](#) [Databases](#)

[New Search](#)

[Back To Search Results](#)

Device	Device, Anti-Snoring
Regulation Description	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.
Regulation Medical Specialty	Dental
Review Panel	Dental
Product Code	LRK
Premarket Review	Office of Device Evaluation (ODE) Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID) Dental Devices Branch (DEDB)
Submission Type	510(k)
Regulation Number	872.5570
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Recognized Consensus Standard	<ul style="list-style-type: none">ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry [Including: Amendment 1 (2013)]
Guidance Document	<ul style="list-style-type: none">Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	<ul style="list-style-type: none">Eligible for Accredited Persons Program
Accredited Persons	<ul style="list-style-type: none">Dekra Certification B.v.Regulatory Technology Services, LlcThird Party Review Group, LlcTuv Sud America Inc.

Product Code Classification Database

Product Classification

[FDA Home](#) [Medical Devices](#) [Databases](#)

New Search		Back To Search Results
Device	Device, Anti-Snoring	
Regulation Description	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.	
Regulation Medical Specialty	Dental	
Review Panel	Dental	
Product Code	LRK	
Premarket Review	Office of Device Evaluation (ODE) Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID) Dental Devices Branch (DEDB)	
Submission Type	510(k)	
Regulation Number	872.5570	
Device Class	2	
Total Product Life Cycle (TPLC)	TPLC Product Code Report	
GMP Exempt?	No	
Recognized Consensus Standard	<ul style="list-style-type: none">ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry [Including: Amendment 1 (2013)]	
Guidance Document	<ul style="list-style-type: none">Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA	
Implanted Device?	No	
Life-Sustain/Support Device?	No	
Third Party Review	<ul style="list-style-type: none">Eligible for Accredited Persons Program	
Accredited Persons	<ul style="list-style-type: none">Dekra Certification B.v.Regulatory Technology Services, LlcThird Party Review Group, LlcTuv Sud America Inc.	

- This page include several key pieces of information:
 - The 7-digit Regulation Number that corresponds to the federal regulation and the link to the Code of Federal Regulations
 - The classification of this device (in this case Class II)
 - Whether the device is exempt from Good Manufacturing Practices (GMP).
 - GMP exempt devices are those for which there is no premarket notification requirement.
 - A link to the Total Product Lifecycle (TPLC), which provides premarket reviews, device problems, and recall information.

Device Panel Database

- **Note that many common search terms will not generate a match within the Product Code Classification Database.**
 - For example, the search term "knee brace" will not match anything in the data base.
 - The same is true for the search term "knee prosthesis."
- **In such cases, it is often preferable to search by Device Panel.**

Device Panel Database

- The FDA has created 16 medical categories, referred to as "panels."
- Each panel corresponds to a section of the Code of Federal Regulations.
- The next page is a table of the panels and the regulatory cite for each.

Device Panel Database

Medical Specialty		Regulation Citation (21CFR)
73	Anesthesiology	Part 868
74	Cardiovascular	Part 870
75	Chemistry	Part 862
76	Dental	Part 872
77	Ear, Nose, and Throat	Part 874
78	Gastroenterology and Urology	Part 876
79	General and Plastic Surgery	Part 878
80	General Hospital	Part 880
81	Hematology	Part 864
82	Immunology	Part 866
83	Microbiology	Part 866
84	Neurology	Part 882
85	Obstetrical and Gynecological	Part 884
86	Ophthalmic	Part 886
87	Orthopedic	Part 888
88	Pathology	Part 864
89	Physical Medicine	Part 890

Device Panel Database

- If you know the panel of the device you are analyzing, it is often easier to use the Device Panel search feature to access information.
- Go to:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm>
- You will see the following:

Device Panel Database

CFR - Code of Federal Regulations Title 21

[FDA Home](#) [Medical Devices](#) [Databases](#)

This database includes:

- a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. Title 21 of the CFR is reserved for rules of the Food and Drug Administration. This database contains content that is current as of April 1 2014. For a daily compilation of CFR and Federal Register amendments, see the [Electronic Code of Federal Regulations](#).

[Learn More...](#)

Search Database

 [Help](#)

Title21 Part.Section
(e.g., 862.1385)

 Full Text Search

CFR Title 21 - Food and
Drugs: Parts 1 to 1499

- (1) General enforcement regulations
- (2) General administrative rulings and decisions
- (3) Product jurisdiction
- (4) Regulation of combination products
- (5) Organization

[Clear Form](#)

Device Panel Database

- Put in the applicable Device Panel code prefix (3-digits) in a search term.
- Using the knee brace example, the Device Panel code would be 888 (Orthopedic) and the search term is “knee brace.”
 - Note that you can also use code 890 (Physical Medicine) with the search term “knee brace” and obtain the same result.

Device Panel Database

CFR - Code of Federal Regulations Title 21

◁ FDA Home ▷ Medical Devices ▷ Databases

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- (3) Product jurisdiction
- (4) Regulation of combination products
- (5) Organization

[Clear Form](#)

Search

Device Panel Database

- This search will produce the desired result of limb orthosis, the 7-digit Device Regulation number, and a link directly to the pertinent Code of Federal Regulations cite.
- You can then use the Device Regulation number to obtain the device classification information, as follows:

Device Panel Database

Product Classification

FDA Home Medical Devices Databases



1 to 5 of 12 Results
890.3475

1 2 3 >

Results per Page 5

[New Search](#)

[Export to Excel](#) | [Download Files](#) | [More About Product Classification](#)

Product Code	Device		Regulation Number	Device Class
ITM	Cage, Knee	Limb Orthosis	890.3475	1
LQX	Device, Finger-Sucking	Limb Orthosis	890.3475	1
ITW	Joint, Ankle, External Brace	Limb Orthosis	890.3475	1
ITS	Joint, Hip, External Brace	Limb Orthosis	890.3475	1
ITQ	Joint, Knee, External Brace	Limb Orthosis	890.3475	1

- When you go to the link for Joint, Knee, External Brace you will see all the key information.
 - This information will confirm that an external knee brace is a Class I device and is, therefore, exempt from the premarket approval requirement.

Device Panel Database

Product Classification

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890.3475

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Product Code	Device		Regulation Number	Device Class
ITM	Cage, Knee	Limb Orthosis	890.3475	1
LQX	Device, Finger-Sucking	Limb Orthosis	890.3475	1
ITW	Joint, Ankle, External Brace	Limb Orthosis	890.3475	1
ITS	Joint, Hip, External Brace	Limb Orthosis	890.3475	1
ITQ	Joint, Knee, External Brace	Limb Orthosis	890.3475	1

Device Panel Database

Product Classification

[FDA Home](#) [Medical Devices](#) [Databases](#)

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Device	Joint, Knee, External Brace
Regulation Description	Limb orthosis.
Regulation Medical Specialty	Physical Medicine
Review Panel	Physical Medicine
Product Code	ITQ
Premarket Review	Office of Device Evaluation (ODE) Division of Neurological and Physical Medicine Devices (DNPMD) Physical Medicine and Neurotherapeutic Devices Branch (PNDB)
Submission Type	510(K) Exempt
Regulation Number	890.3475
Device Class	1
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 <i>not</i> labeled or otherwise represented as sterile.</p>	
<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

Investigational Device Exemption (IDE)

- An investigational device exemption (IDE) allows the investigational device to be used in the clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) Application or a Premarket Notification 510(k) submission to the FDA.
 - 21 CFR Part 812
- Clinical studies with devices of significant risk must be approved by FDA and by an institutional review board (IRB) before the study can begin.
 - Studies with devices of non-significant risk must be approved by the IRB only before the study can begin.

Quality System Regulation/Good Manufacturing Practices

- Manufacturers must establish and follow quality systems (QS) to help ensure that their products consistently meet applicable requirements and specifications.
- The quality systems for FDA-related products (food, drugs, biologics, and devices) are known as current good manufacturing practices (CGMPs).
 - 21 CFR Part 820.

QS Regulation

- Because the QS regulation must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device.
- Rather, the QS regulation provides the framework that all manufacturers must adopt by requiring that manufactures develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device.
 - Manufacturers are to use good judgment in developing their quality system and apply those sections of the QS regulation that are applicable to their specific product and operations (21 CFR 820.5).

Applicability of the QS Regulation

- The QS regulation applies to finished device manufacturers who intend to commercially distributed medical devices.
 - A finished device is defined in **21 CFR 820.3 (I)** as any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.
 - Certain components such as blood tubing and diagnostic x-ray components are considered by FDA to be finished devices because they are accessories to finished devices.
 - Accordingly, a manufacturer of accessories is subject to the QS regulation.

GMP Exemptions

- FDA has determined that certain types of medical devices are exempt from GMP requirements.
 - These devices are exempted by FDA classification regulations published in the Federal Register and codified in [21 CFR 862-892](#).
 - Exemption from the GMP requirements does not exempt manufacturers of finished devices from keeping complaint files ([21 CFR 820.198](#)) or from general requirements concerning records ([21 CFR 820.180](#)).
 - Medical devices manufactured under an investigational device exemption are not exempt from design control requirements under [21 CFR 820.30](#) of the QS regulation.

Labeling

- Labeling regulations pertaining to medical devices are found in the following Parts of Title 21 of the Code of Federal Regulations:
 - General Device Labeling - [21 CFR Part 801](#)
 - In Vitro Diagnostic Products - [21 CFR Part 809](#)
 - Investigational Device Exemptions - [21 CFR Part 812](#)
 - Unique Device Identification - [21 CFR Part 830](#)
 - Good Manufacturing Practices - [21 CFR Part 820](#)
 - General Electronic Products - [21 CFR Part 1010](#)

Label vs. Labeling and Advertising

- Section 201 (k) defines "label" as a:
 - “Display of written, printed, or graphic matter upon the immediate container of the article . . .”
 - The term "immediate container" does not include package liners.
 - Any word, statement, or other information appearing on the immediate container must also appear on the outside container or wrapper or be easily legible through the outside container.
- Section 201 (m) defines "labeling" as:
 - All labels and other written, printed, or graphic matter:
 - upon any article or any of its containers or wrappers, or
 - accompanying such article at the time while the device is held for sale after shipment or delivery for shipment in interstate commerce.
 - Extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc.
- Beware, according to an appellate court decision: “Most, if not all advertising, is labeling.”

Mandatory Medical Device Reporting

- The Medical Device Reporting (MDR) regulation (**21 CFR 803**) contains mandatory requirements for manufacturers, importers, and device user facilities to report certain device -related adverse events and product problems to the FDA.
- By a new regulation that became effective in August 2015, specified reports must be filed on FDA MedWatch Form 3500A or an electronic equivalent that the FDA can process, review, and archive.

Mandatory Medical Device Reporting

- **Manufacturers:** manufacturers are required to report to the FDA when they learn that any of their devices may have caused or contributed to a death or serious injury.
 - Key terms are defined in [21 CFR 803.3](#).
 - Instructions are available for completing the required 3500A form.
 - Manufacturers must also report to the FDA when they become aware that their device has malfunctioned or will be likely to cause or contribute to death or serious injury if the malfunction were to occur.
 - For additional information see the draft guidance at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359130.htm>
- **Importers:** importers are required to report to the FDA and the manufacturer when they learn that one of their devices may have caused or contributed to a death or serious injury.
 - The importer must report only to the manufacturer if their imported devices have malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to occur.

Summary of Mandatory Reporting Requirements

Summary of Mandatory Reporting Requirements for Manufacturers and Importers

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
Manufacturers	30 day reports of deaths, serious injuries and malfunctions	Form FDA 3500A *	FDA	Within 30 calendar days of becoming aware of an event
	5-day reports for an event designated by FDA or an event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health	Form FDA 3500A *	FDA	Within 5 work days of becoming aware of an event
Importers	Reports of deaths and serious injuries	Form FDA 3500A *	FDA and the manufacturer	Within 30 calendar days of becoming aware of an event
	Reports of malfunctions	Form FDA 3500A *	Manufacturer	Within 30 calendar days of becoming aware of an event

* Or electronic equivalent

Device User Facility Reporting Requirements

- A device user facility is a hospital, laboratory, surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician's office.
- User facilities must report a suspected medical device - related death to both the FDA and the manufacturer.
- User facilities must report a medical device -related serious injury to the manufacturer, or to the FDA if the medical device manufacture is unknown.

Device User Facility Reporting Requirements

- User facilities must also submit annual reports to the FDA by January 1 of each year as described in section **803.33**.
- The Medical Device Reporting Annual User Facility Report (Form FDA 3419) is available at:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm>
- Instructions for Completing the Medical Device Report Annual User Facility Report, FDA 3419 is available at:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm385881.htm>

Device User Facility Reporting Requirements

- Section 803.3 (which addresses User Facility Reporting Requirements) does not state that device user facilities are required to report device malfunctions where the malfunction would likely cause or contribute to death or serious injury if the malfunction were to occur.
- Although user facility is not required to report a device malfunction, it can voluntarily inform the FDA of such product problems through MedWatch, the FDA's Safety Information and Adverse Event Reporting Program.
 - Providers within a user facility should be familiar with the institution's procedures for reporting adverse events to the FDA.
- More information is available at the FDA's guidance "Medical Device Reporting for User Facilities" available at:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm>

Summary of Mandatory Reporting Requirements for User Facilities

Summary of Mandatory Reporting Requirements for User Facilities

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
User Facility	Device-related Death	Form FDA 3500A	FDA & Manufacturer	Within 10 work days of becoming aware
User Facility	Device-related Serious injury	Form FDA 3500A	Manufacturer. FDA only if manufacturer unknown	Within 10 work days of becoming aware
User Facility	Annual summary of death & serious injury reports	Form FDA 3419	FDA	January 1 for the preceding year

Complaint Files and Medical Device Reporting

- Complaint files are linked to MDR event files because a complaint must be evaluated to determine if it is a reportable adverse event.
 - A complaint is any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.
 - Manufacturers and importers are required to maintain complaint files and establish and maintain procedures for receiving, reviewing, and evaluating complaints.
 - Importers are also subject to complaint files because initial distributors of foreign entities fall under the definition of a manufacturer in [21 CFR 820.3](#).

Electronic Medical Device Reporting (eMDR)

- Detailed information about how to submit MDRs electronically is available on the eMDR website.
- Guidance for Industry, User Facilities and FDA Staff: eMDR – Electronic Medical Devices Reporting is available at:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm175805.htm>
- The Final Rule on Electronic Medical Device Reporting (eMDR) is available at:
<https://www.federalregister.gov/articles/2014/02/14/2014-03279/medical-device-reporting-electronic-submission-requirements>
- Inquiries can also be made by phone (301-796-6670) or email to MDRPolicy@fda.hhs.gov

Reporting an Emergency

- **If you have identified a public health emergency, you can notify the FDA Office of Crisis Management, Emergency Operations Center**
 - **Voice (24/7) phone: 866-300-4374 or 301-796-8240**
 - **FAX: 301-847-8543**

Searching Medical Device Reports

- The FDA maintains the Manufacturer and User Facility Device Experience (MAUDE) database that contains mandatory reports filed by manufacturers and importers from August 1996 to present, all mandatory user or facility reports from 1991 to present, and voluntary reports filed after June 1993.
 - The MAUDE database houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.
 - While the database is a valuable source of information, it is a passive surveillance system and has limitations, including potential submission of incomplete, inaccurate, untimely, unverified, or biased data.
 - MAUDE is available at:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>

Concluding Thoughts

- When developing a new device, develop a plan well in advance. The plan should include:
 - A detailed product launch plan;
 - A realistic time line, including all necessary steps and an allowance for unexpected events;
 - A communications plan that identifies and involves all necessary personnel;
 - A thorough budget specific to the particular device, including the costs of clinical trials, evaluations and FDA submissions;
 - A training schedule.
- When dealing with the FDA, the old adage "it is better to ask for forgiveness then permission" is fraught with risk.
 - In my experience it is a much better strategy to work with the FDA, including notifying the FDA of any problems, rather than ignoring potential issues.
 - The FDA responds much more favorably to notification and a well developed plan to address issues than it does to independently discovering unaddressed issues.

Additional Holland & Hart Resources

- Future webinars
 - 5/19/16 **Board Training Part I**
 - 5/26/16 **Cross-State Licensure for Providers**
- *Healthcare Update* and *Health Law Blog*
 - Under “Publications” at www.hollandandhart.com
 - To subscribe, go to www.hollandandhart.com or e-mail me at pdean@hollandandhart.com

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