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Regulatory Pathway for Class I Medical Device Elastic Bandage in Usa

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KEYWORDS

CDRH- Centre for Devices and Radiological Health, FDA and PMA

ABSTRACT:

Regulatory body of medical device in the globe is USFDA. According to USFDA in USA medical devices are enforced by CDRH- Centre for Devices and Radiological Health. In USA medical device Regulatory pathway varies based on intended use. Depending on the risk of patient medical devices in USA are divided into 3 classes. Class 1 medical devices are low risk devices. The example of class 1 medical devices is Elastic Bandages is having different regulatory pathway and approval process. To get FDA approval of Elastic Bandage is does not require premarket notification 510(k) and PMA (pre-Market Approval) due to low risk device class, the steps involved in approval from FDA for class 1 devices are device registration, listing, and fee payment, which are must be renewal for every year.

1. INTRODUCTION

Medical Device Definition: Medical device is defined by FDA in NF or USP is an instrument, equipment, implement, machine, mechanism, implant, in vitro reagent, or other object that is comparable or related, including an accessory or component. A medical device can be used to diagnose illness or other disorders, and to treat them and mitigate their effects and prevent them in both humans and animals

Regulatory Authority: FDA's CDRH- Center for devices and Radiological Health regulates the companies to produce, repackage, relabel, import or sold in US. The CDRH controls the use of radiation in both medical and non-medical electronic items, including color televisions, Lasers, X-rays, Ultrasound devices and micro-ovens.

Medical Device Classification: -The FDA classified around 1700 dissimilar generic devices and placed them interested in 16 medical expertise known as panels. Depending upon the level of command required for the safety and efficacy of device.

These generic equipment's are classified into 3 regulatory classes

Class	Controls
Class I	General controls with or without exemptions
Class II	General and special controls with or without exemptions
Class III	General controls and premarket approval

The above classification shows the kind of premarketing application is required by FDA authorization. Device will need a 510k in order to market if it's categorized as Class I or II and is not exempt. The restriction on exemptions applies to all devices that are designed as exemptions apply to all devices that are designated as

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exempt. If product is a preamendment device and PMAs not accepts to a Premarket Approval Application (PMA) A 510k will be the best way to market

The designed use of medical equipment shows its classification. As an example, Scalpel is used for the purpose of cutting tissue. A specific indication such for making incision in the cornea is added to the device label. The device label contains its usage, but they also be discussed verbally when the product is being sold. In premarketing notification; the 510k program: includes Evaluating Substantial Equivalency.

Medical devices risk based classification, what patient or user experience

Class I and II are less risk and class III are high risk

These divided classes are subjected to General Control and Baseline requirements of FDA act

S.no	Class	Degree of risk	Illustrations
1	Less risk	Less risk	Bandages , tongue depressors
2	Moderate risk	Moderate risk	Powered wheelchairs, Infusion pumps
3	High risk	High risk	Pacemakers, Implantable defibrillators

Determination of Classification:

To determine the classification of medical device and any potential exemptions, know the regulation number corresponding classification of medical device regulation

Identifying equipment and regulation matching can be done in 2 ways

Enter the device name in full and conduct a search in the classification database

Find our medical device belongs to which medical speciality equipment panel go straight to the panels listing and identify device

We are already aware of the relevant panel. If unsure can utilize the product code classification data base keyword dictionary. Alternatively, may depart straight to the CFR and find the categorization for look through the list of classified products to find a medical device. The database will also identify the CFR categorization regulation. For further details on particular items and how CDRH regulates them, shows the regulation classification below

A list of devices includes in each CFR. Each classified equipment assigned a 7-digit number, such as the clinical Mercury Thermometer's 21 CFR 8802920

Once our medical device enlisted in the list; navigate to the section mentioned in the sample 21 CFR 8802920. The device is described and identified as class II. Similar to this you can find multiple entries for different kinds of thermometers under the term THERMOMETER in the classification of database. In the clinical thermometer database, the medical device is listed in the form of 3 letter product code FLK serves as both the categorization number and the product code

Regulation classification is determined by using, either visit of CFR search page or navigate to what are the classification panels below and appropriate regulation. Certain class I devices are exempted from GMP and premarket notification requirements. Premarket notification is not required for about 572, or 74%of class I devices. The documented medical device exemptions are 21 CFR classification regulations.

Regulatory Pathway for class I medical equipments in US

As per above classification. Class I drugs are with no risk and it is safe to patient and needs very little regulatory in the US and EU. Medical devices like bandages, wheelchairs, and surgical instruments are in risk class I

This class I medical devices in US does not require any specific post market requirements

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Regulatory Requirements for class I medical Devices:
-

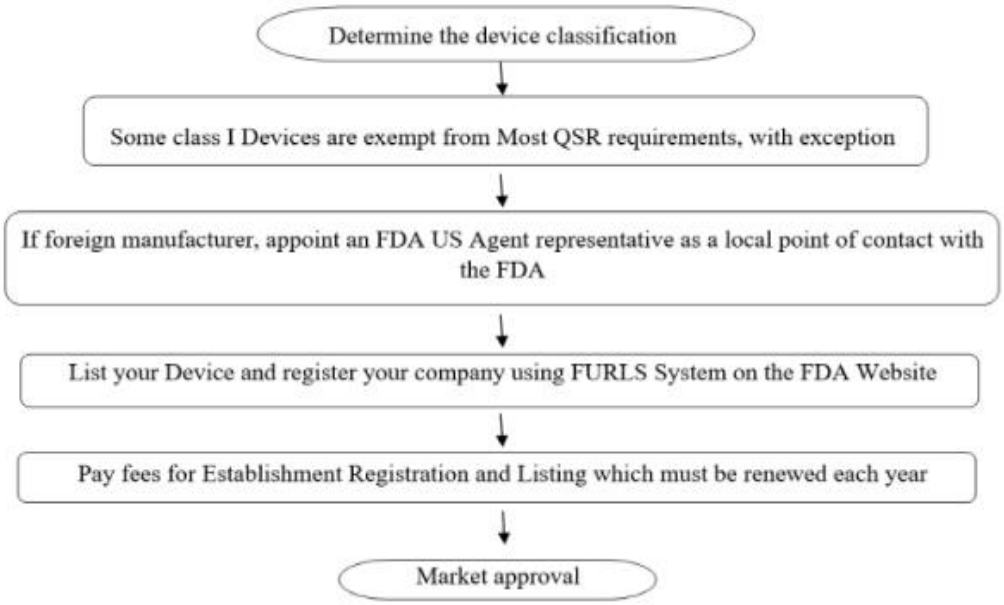
According to the FDA registration class I goods must follow procedures and distribution, Class I medical equipments are free from 110k requirements FDA'S categorization standards specifications for their particular product. Manufactures and distributors of class I medical devices are non-etheless bound by FDA regulations regarding marketing clams. The FDAS device loss per training to adulteration, misbranding and making false or misleading claims still apply to these goods. The FDA rejects medical equipments in classI are not FDA approved

Regulatory timelines for registering class I devices

Class I devices are less complex manufactures and distributers can register their business and list their business and list their devices on the FDA'S Establishment and Device listings and start distributing their product right away if they have items with the necessary production controls manufactures and distributors must relist their products every year.

2. DISCUSSION:

Regulatory Flow chart for class I devices:



Definition for class I medical device:

According to FDA class I medical devices defines as they are not designed for using supportive or sustain life of major rank in avoiding impairment to human health and they may not provide a possible unjustifiable danger of sickness or damage

Medical device class I make up around half of all medical devices subjective FDA Regulations

A medical device classified as class I which as a less risk benefit ratio. this indicates that there are serious side effects or injuries linked to the miss use of these well-established products medical device of class I which diagnosis may not change some one's course of life because they are neither life sustaining nor life supporting. medical devices include bandages, tooth brushes as well as hospital items such as bed paints comes under class I.

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Examples: Examples of Class 1 medical devices include:

- Stethoscopes
- Bedpans
- Latex gloves
- Surgical masks
- Elastic Bandages
- Bandages
- Tongue depressors
- Irrigating dental syringes

Selection of Class I Medical Device:

In this research work I selected the **Elastic Bandage.**

Class I Device: Elastic Bandage[6]

Description[10]: General Hospital and Personal Use Devices

Subpart F - General Hospital and Personal Use Therapeutic Devices

Sec. 880.5075 Elastic Bandage.

(a) Identification: - Elastic bandage is an instrument used to compress and support patients body part. It can be a long, flat ship or elasticized material tube

(b) Classification: - class I General control subject to the restrictions in 850-9 a premarket notification done by this device requirements subpart e of part 807 additionally the device is free from ongoing good manufacturing practice and quality system regulations which are in part of 820 of this chapter from the exception of 820.180 regarding general in complaint files .

New Search Help | More About 21CFR

[Code of Federal Regulations]
[Title 21, Volume 8]
[CITE: 21CFR880.5075]

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 880 -- GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart F - General Hospital and Personal Use Therapeutic Devices

Sec. 880.5075 Elastic bandage.

(a) *Identification.* An elastic bandage is a device consisting of either a long flat strip or a tube of elasticized material that is used to support and compress a part of a patient's body.

(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 § 880.9. The device also is 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, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 38804, July 25, 2001]

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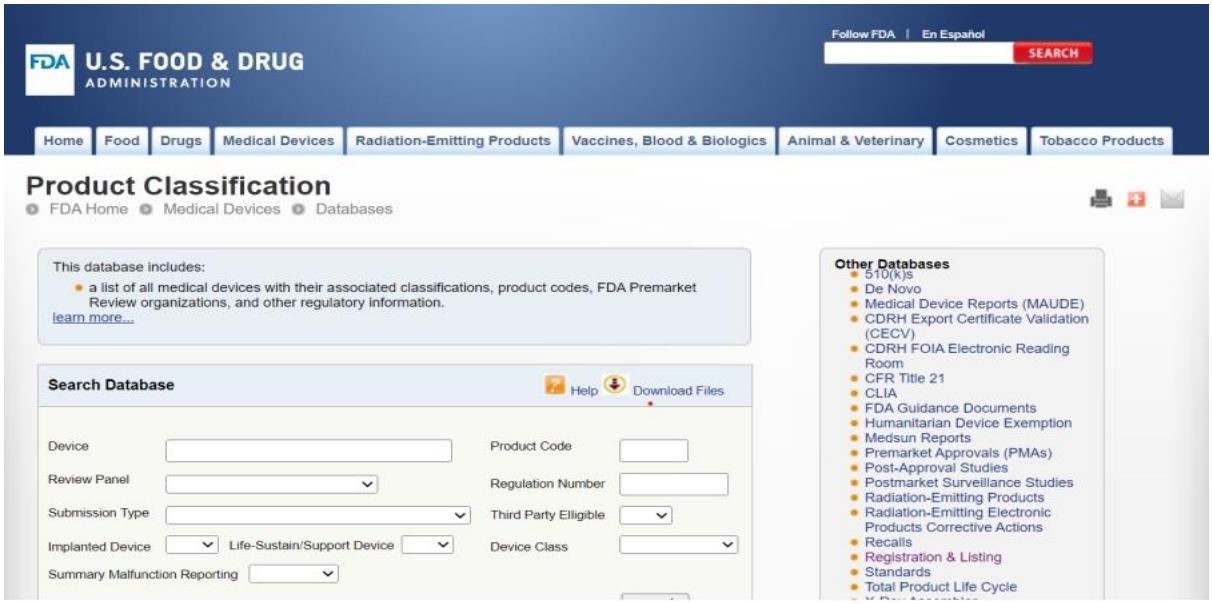

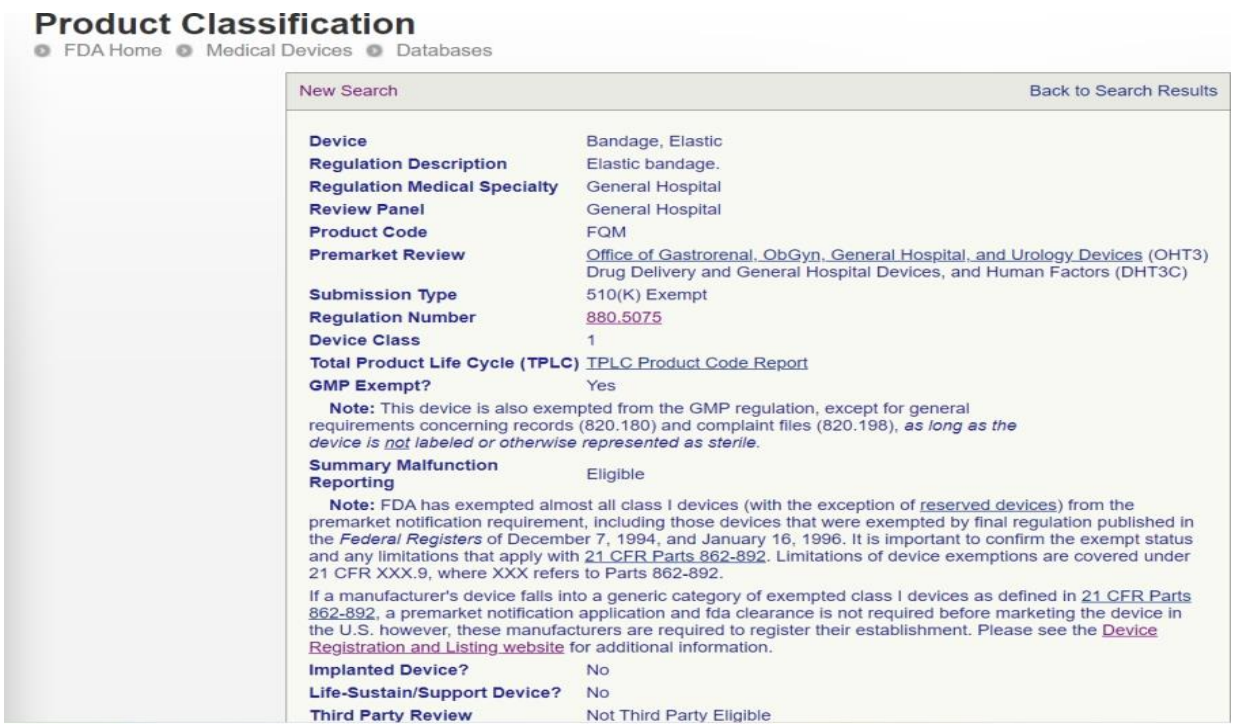

Device classification panels:

By referring title 21 of the code of Federal Regulation categorized majority of medical devices and determining appropriate prescription for the device. In the CFR as categorised and characterised more than 1700 different kinds of devices arranging them into 16 panels refers as specialised equipments such as cardiovascular ,ear,nose,and throat equipments the CFR'S parts 862 through 892 contain these panels the FDA classification (CFR) general overview of each equipment ,together with information regarding its intended application categorisation regulation of medical device definition found in part 862-892 of 21CFR.

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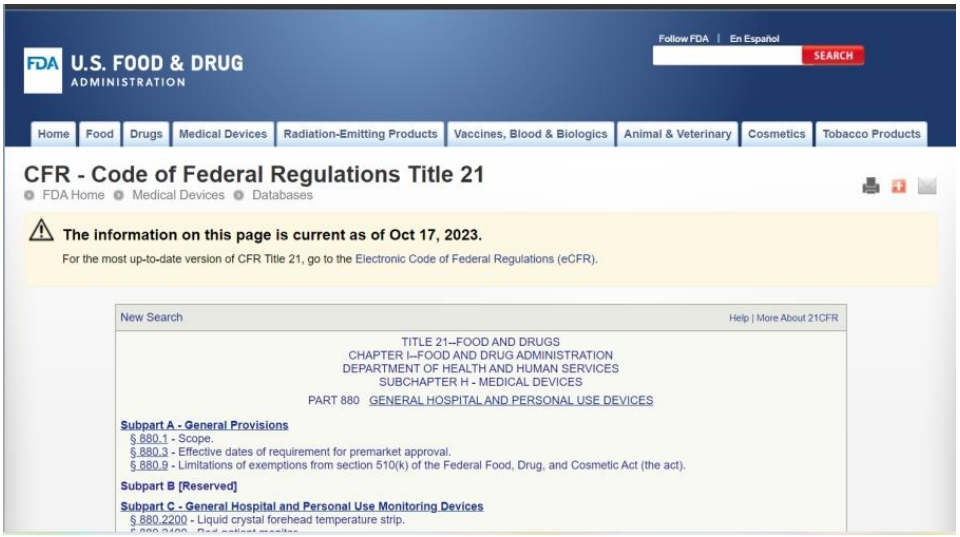
Classification regulations:

Sl No	Medical speciality		Regulation Citation(21CFR)
1	73	Anaesthesiology	Part 868
2	74	Cardiovascular	Part 870
3	75	Chemistry	Part 862
4	76	Dental	Part 872
5	77	Ear, Nose and Throat	Part 874
6	78	Gastroenterology and Urology	Part 876
7	79	General and Plastic Surgery	Part 878
8	**80**	**General Hospital**	**Part 880**
9	81	Haematology	Part 864
10	82	Immunology	Part 866
11	83	Microbiology	Part 866
12	84	Neurology	Part 882
13	85	Obstetrical and Gynaecological	Part 884
14	86	Ophthalmic	Part 886
15	87	Orthopaedic	Part 888
16	88	Pathology	Part 864
17	89	Physical Medicine	Part 890
18	90	Radiology	Part 892
19	91	Toxicology	Part 862

Product Sub Part with Section[9]



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SUBCHAPTER H - MEDICAL DEVICES

PART 880 GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart A - General Provisions
§ 880.1 - Scope.
§ 880.3 - Effective dates of requirement for premarket approval.
§ 880.9 - Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B [Reserved]

Subpart C - General Hospital and Personal Use Monitoring Devices
§ 880.2200 - Liquid crystal forehead temperature strip.
§ 880.2400 - Bed-patient monitor.
§ 880.2420 - Electronic monitor for gravity flow infusion systems.
§ 880.2460 - Electrically powered spinal fluid pressure monitor.
§ 880.2500 - Spinal fluid manometer.
§ 880.2700 - Stand-on patient scale.
§ 880.2720 - Patient scale.
§ 880.2740 - Surgical sponge scale.
§ 880.2750 - Image processing device for estimation of external blood loss.
§ 880.2800 - Sterilization process indicator.
§ 880.2900 - Clinical color change thermometer.
§ 880.2910 - Clinical electronic thermometer.
§ 880.2920 - Clinical mercury thermometer.
§ 880.2930 - Apgar timer.

Subparts D-E [Reserved]

Subpart F - General Hospital and Personal Use Therapeutic Devices
§ 880.5025 - I.V. container.
§ 880.5045 - Medical recirculating air cleaner.
§ 880.5075 - Elastic bandage.
§ 880.5090 - Liquid bandage.
§ 880.5100 - AC-powered adjustable hospital bed.
§ 880.5110 - Hydraulic adjustable hospital bed.
§ 880.5120 - Manual adjustable hospital bed.
§ 880.5130 - Infant radiant warmer.
§ 880.5140 - Pediatric medical crib.
§ 880.5145 - Medical bassinet.
§ 880.5150 - Nonpowered flotation therapy mattress.

Medical Device (Elastic Bandage) Exemptions 510(k) and GMP Requirements[11]

The good manufacturing practice (GMP)/ quality system exemptions and 510(k)exempt devices are broken down per device class below.

These lists devices are all 510 (k) exempt

Class I devices

The premarket notification requisite nearly all devices of class I have been exempted by the FDA .the devices and regulations were published federal Registers on December 7 1994 and January 16 1996 verifying the exempt status and any applicable limits with reference to 21 CFR parts 862-892 is crucial 21 CFR xxx 9 addresses the limitations of device exemptions.

In united states before marketing an equipment a producers device may be marketed with out a application from premarket or FDA clearance if it fix into one of the general categories of exempted class 1 devices as specified in 21 CFR parts 862- 892 .these manufactures however register their business and provide and general category name .to submit registration and listing information entitled in the FDA'S unified registration and listing system (FURLS)/Device registration and listing module(DRML)

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Class I Exempt Devices:

Part 610	General biological products standards
Part 660	Additional standards for diagnostic substances for laboratory tests
Part 862	Clinic 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

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Medical Device Exemptions 510(k) and GMP Requirements

FDA Home ❯ Medical Devices ❯ Databases

Introduction

Following is a breakdown of 510(k) exempt and Good Manufacturing Practice (GMP)/Quality System exemptions listed by device class. All devices in this list are 510(k) exempt unless further qualified by a footnote. Only devices annotated by (*) are also exempt from GMP except for general recordkeeping requirements and compliant files.

Class I Devices

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. Some 510(k) exemptions annotated with "**&**" are with certain limitations as noted in the footnotes. 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 and list the generic category or classification name. Registration and listing information is submitted by using FDA's Unified Registration and Listing System (FURLS)/ Device Registration and Listing Module (DRLM) at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm

IMPORTANT NOTE: Only the class I devices with an asterisk (*) are 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*.**

Class II Devices

The Food and Drug Administration (FDA) has also published a list of class II (special controls) devices (those devices are annotated as "(II)"), subject to certain limitations, that are exempt from premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (FDAMA) or the 21st Century Cures Act of 2016 (Cures Act).

Class I and Class II Exempt Devices

PART 610	GENERAL BIOLOGICAL PRODUCTS STANDARDS
PART 660	ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS
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

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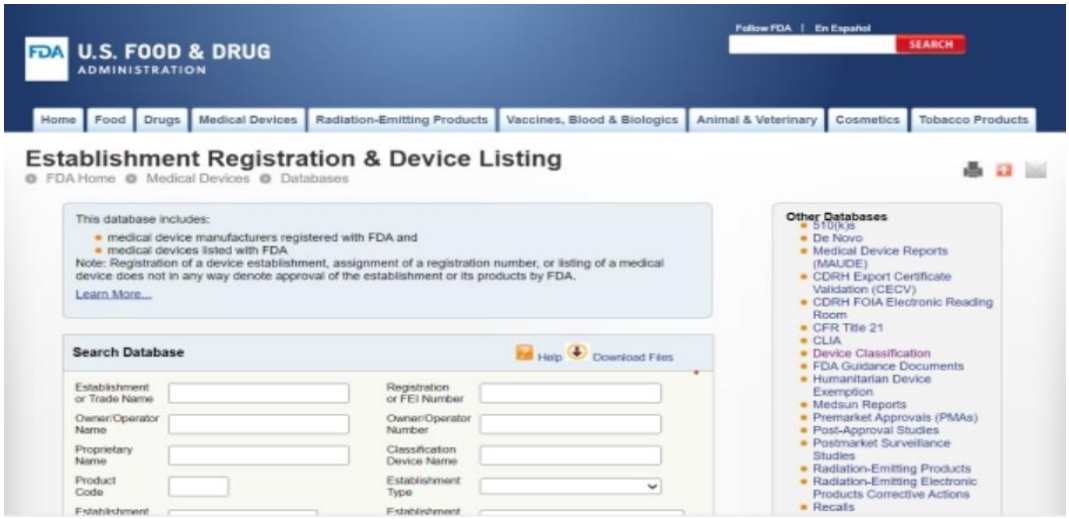
Appoint US Agent:

Establishment of Device registration for manufacturing, distribution and sale in USA appoint one US agent. US agent is submitting by electronic system using the FURLS System.

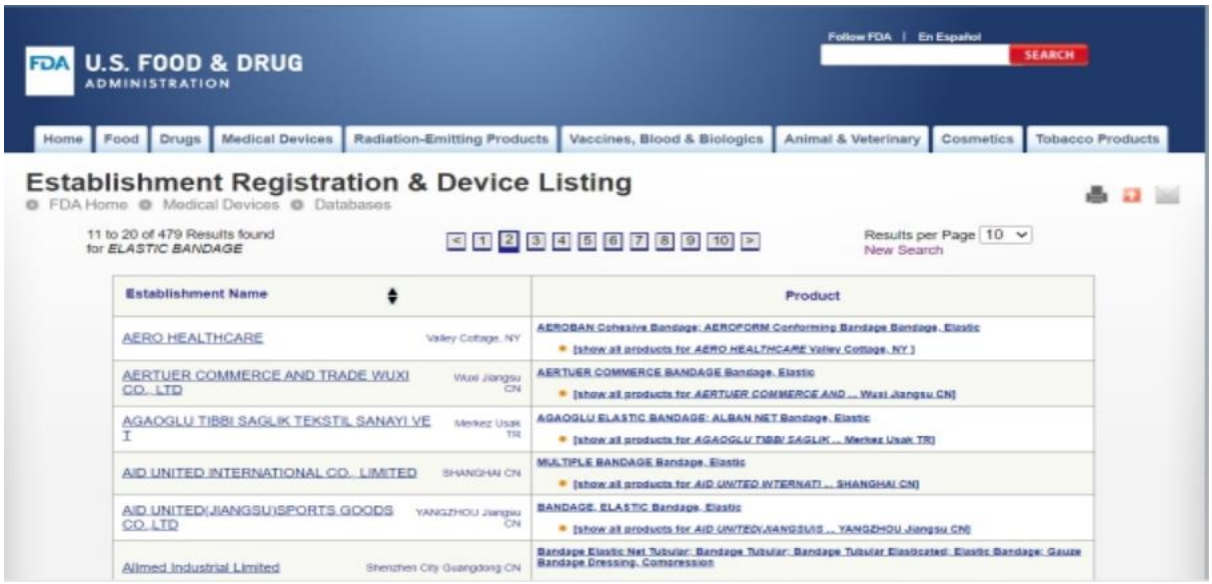
Device Registration and Listing[12]:

According to Title 21 CFR Part 807, this procedure is called establishment registration. Owner and operators of business intricate in the making and supply of medical devices proposed for usage within the United States are essential to register with the FDA on an annual basis Congress has authorized the FDA to charge an annual establishment registration fee from device establishments. An extensive list of the different types of device establishment that must register and pay the fee

Establishment Registration[13]:



Establishment Registration[14]:



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Device Registration Fee[15]:

According to the Food and Drug Administration Amendments Act (FDAAA) of 2007, unless the FDA grants a waiver, Annual, Initial, and updated information and all registration must be filed online. Businesses that offer medical equipment are required to register in two phases. To register for an annual account, first you should pay the user fee.

Once payment has been made, complete the process of registration. First pay the yearly registration fee then your registration will be considered, registration details and listing details are submit through electronically. FDA will verify and send a mail if all the requirements fulfill.

Annual registration fee payment

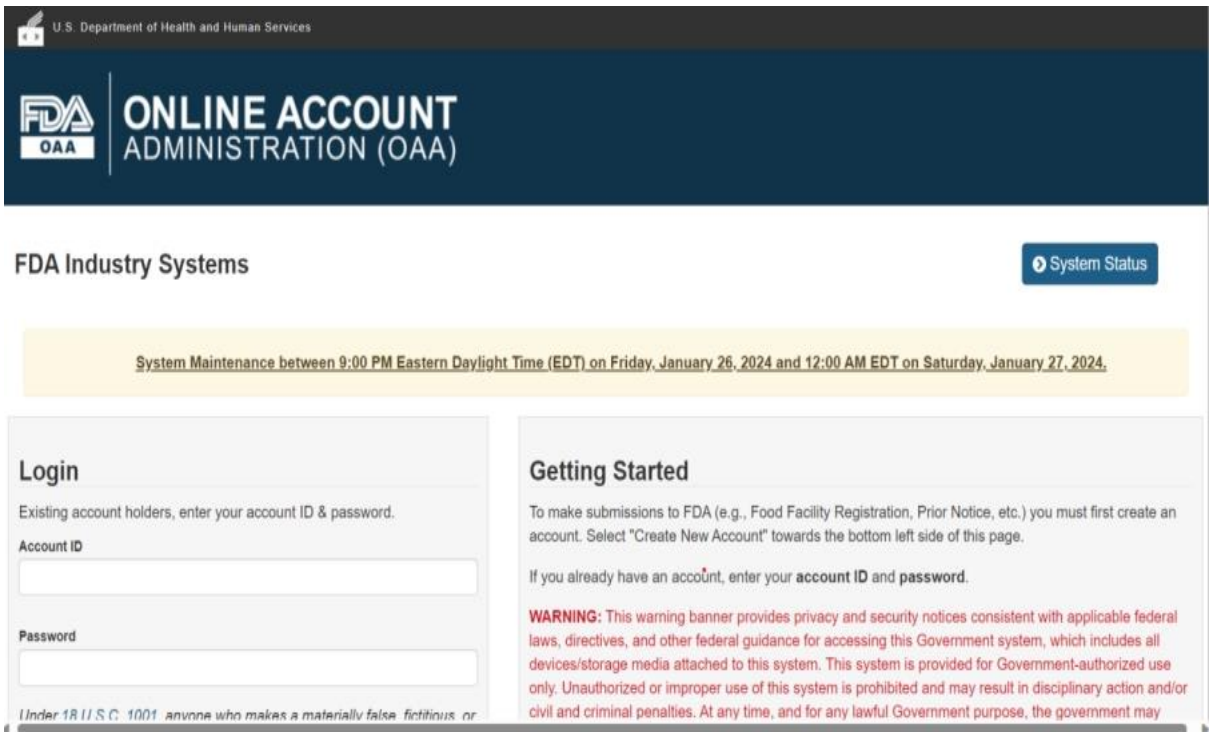
Payment of annual registration fee online is available on the DFUF Website. (Device Facility User Charge). You will get a Payment Identification Number (PIN) on the DFUF website when you make a payment. An email verifying the transaction and with details on how to obtain your Payment Confirmation Number (PCN) will be sent to you after your payment has been finalized. Due to the possibility of multiple day processing, please ensure payment at least a few days prior to enrolling. To find out more information, see the Payment Process. As soon as you have payment confirmation, you can register your establishment.

Registering Facility

Submission of Device Registration and listing information only through the FURLS and DRLM. Each possessor or operative should have an account credentials (ID and password) in order to use FURLS. The proprietor or manager needs to draft an If someone else has been designated as the official correspondent, they should have a subaccount with a special credentials for them.

FURLS- FDA's Unified Registration and Listing System

Device Registration and Listing Module (DRLM)



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11. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm
12. https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing
13. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
14. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/TextResults.cfm?dls=11&q=RUxBU1RJQyBCQU5EQUdF & amp; pf=0& pn=10& sc=ena
15. https://www.fda.gov/medical-devices/device-registration-and-listing/how-register-and-list
16. https://www.fda.gov/medical-devices/device-registration-and-listing/payment-process