Class I and Class II medical devices:

Defining, classifying and marketing them

Report by

FIME

By Informa Markets

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One of the biggest challenges the manufacturers and/or distributors who attend the **Florida International Medical Expo (FIME)** face when they intend to sell medical devices in the U.S. market, is gaining FDA clearance to market their medical devices. Not only is the process lengthy and costly, but many companies do not have a clear understanding of how to go about applying for approval.

The Food and Drug Administration (FDA) is the regulatory body governing medical devices with a variety of enforcement tools at its disposal, such as seizure, injunction, prosecution and civil penalties.

This brief serves as a quick guide for the FIME audience on how and where to submit an application, as well as information about device classification, required documentation, approval processes, and application fees, among others.

A history of medical device regulation & oversight in the U.S.

1906: Pure Food and Drugs Act (sometimes also called the Federal Food and Drugs Act)

1938: Federal Food, Drug, and Cosmetic Act (FD&C Act)

1944: Public Health Service Act

1968: Radiation Control for Health and Safety Act

1976: Medical Device Amendments to the FD&C Act

1990: Safe Medical Devices Act (SMDA)

1992: Mammography Quality Standards Act (MQSA)

1997: Food and Drug Administration Modernization Act (FDAMA)

2002: Medical Device User Fee and Modernization Act (MDUFMA)

2007: Food and Drug Administration Amendments Act (FDAAA)

2012: Food and Drug Administration Safety and Innovation Act (FDASIA)

2016: 21st Century Cures Act

2017: Food and Drug Administration Reauthorization Act (FDARA)

Medical device classification

According to U.S. law, a medical device is “any article intended for use in diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals”.

The Food and Drug Administration (FDA) has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialities referred to as panels. Each of these generic types of devices is assigned to a three-tier system, first introduced under the Medical Device Amendments of 1976, comprising three categories: Class I, Class II, and Class III. We will be focusing on Class I and Class II medical devices in this report.

Device Class and Regulatory Controls:

Class I subject to General Controls (low-risk devices)	Class II subject to General Controls and Special Controls (modest-risk devices)
• Establishment registration • Device listing • 510(k) pre-market notification (many Class I devices are exempt) • Good Manufacturing Practices (GMP) • Medical Device Reporting	• Post-clearance requirements such as tracking and patient registries • Performance standards • Any other controls that the FDA deems to be appropriate

All manufacturers and/or distributors intending to sell medical devices in the U.S. market must submit their products to the FDA for classification and must satisfy the regulatory controls associated with the class into which the given product falls.

Device classification depends on the *intended use* of the device and also upon *indications for use*. Furthermore, classification is risk-based, that is, the risk the device poses to the patient, and the user is a major factor in the class it is assigned.

As indicated above, all classes of devices are subject to General Controls. General Controls are the baseline requirements of the Food, Drug and Cosmetic (FD&C) Act that apply to all medical devices, Class I, II, and III.

How to determine classification

To find the classification of your device, as well as whether any exemptions may exist, you need to find the regulation number that is the classification regulation for your device.

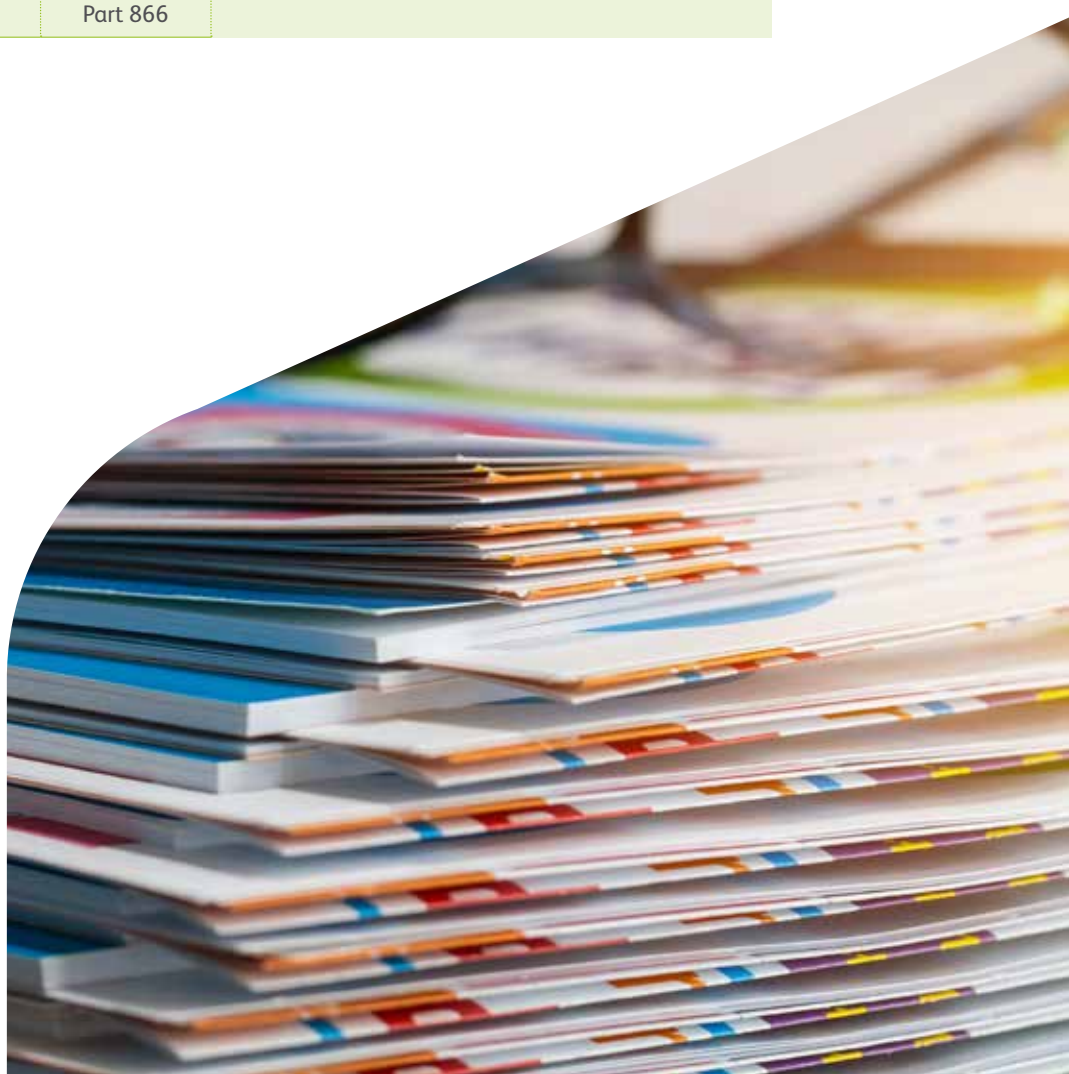
There are two methods for accomplishing this:

- Go directly to the classification database and search for a part of the device name
- If you know the device panel (medical specialty) to which your device belongs, go directly to the listing for that panel and identify your device and the corresponding regulation.

How to locate classification regulations

Most medical devices can be classified by finding the matching description of the device in Title 21 of the Code of Federal Regulations (CFR), Parts 862-892. These specialty "panels" are found in Parts 862 through 892 in the CFR.

Medical specialty		Regulation Citation	Medical specialty		Regulation Citation
73	Anesthesiology	Part 868	83	Microbiology	Part 866
74	Cardiovascular	Part 870	84	Neurology	Part 882
75	Chemistry	Part 862	85	Obsterical & Gynecological	Part 884
76	Dental	Part 872	86	Ophthalmic	Part 886
77	Ear, Nose, & Throat	Part 874	87	Orthopedic	Part 888
78	Gastroenterology and Urology	Part 876	88	Pathology	Part 864
79	General and Plastic Surgery	Part 878	89	Physical Medicine	Part 890
80	General Hospital	Part 880	90	Radiology	Part 892
81	Hematology	Part 864	91	Taxicology	Part 862
82	Immunology	Part 866			



Premarket notification 510(K)

Each person who wants to market a Class I and II device intended for human use in the U.S., for which a Premarket Approval application (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the FD&C Act and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9).

There is no 510(k) form; however, 21 CFR 807 Subpart E describes requirements for a 510(k) submission.

A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA.

A legally marketed device is a device that was legally marketed prior to May 28, 1976 (pre-amendment device), or a device which has been reclassified from Class III to Class II or I, a device which has been found safe and effective through the 510(k) process, or a device that was granted marketing authorization via the De Novo classification process under section 513(f)(2) of the FD&C Act, that is not exempt from premarket notification requirements.

Until the submitter receives an order declaring a device safe & effective, the submitter may not proceed to market the device. The safe & effective determination is usually made within 90 days and is made based on the information submitted by the submitter.

It should be noted that the FDA does not perform 510(k) pre-clearance facility inspections. The submitter may market the device immediately after 510(k) clearance is granted. The manufacturer should be prepared for an FDA quality system (21 CFR 820) inspection at any time after 510(k) clearance.

The following four categories of parties must submit a 510(k) to the FDA:

- Domestic manufacturers introducing a device to the U.S. market
- Specification developers introducing a device to the U.S. market
- Repackers or relabelers who make labeling changes or whose operations significantly affect the device.
- Foreign manufacturers/exporters or U.S. representatives of foreign manufacturers/ exporters introducing a device to the U.S. market.

Quality In 510(k) Review Program

The Quality in 510(k) 'Quik' Review Program provides an alternate method to submit a pre-market notification (510(k)) to the FDA using the eSubmitter software to format the submission. The FDA has identified a list of product codes that are eligible. The goal is for the FDA to make a final decision within 60 days of receipt of a 510(k) for an eligible device.

Exemptions

Premarket notification 510(K) exemptions

Certain Class I and Class II devices are exempt from 510(k) requirements as well as the Medical Device Good Manufacturing Practices (GMPs), also referred to as the Quality System (QS) Regulation.

A Class I or Class II device that is exempt from 510(k) requirements must still comply with other requirements (known as regulatory controls) unless the device is explicitly exempt from those requirements as indicated in the regulation for that device type.

Anyone can determine whether a device is exempt from 510(k) or GMP requirements by searching the FDA's Product Classification database.

Most Class I and some Class II devices are exempt from 510(k) requirements, subject to certain limitations (see sections 510(l) and 510(m) of the FD&C Act. A device may be exempt from 510(k) requirements if the FDA determines that a 510(k) is not required to provide reasonable assurance of safety & effectiveness for the device.

Devices which may be exempt from 510(k) requirements are:

- Preamendments devices
- Class I and Class II devices specifically exempted by the FDA.

The term "preamendments device" refers to a device legally marketed in the U.S. before the enactment of the Medical Device Amendments on May 28, 1976, and that has not been:

- Significantly changed or modified since then
- for which the FDA has not determined a PMA application is needed to provide reasonable assurance of the device's safety & effectiveness.

A listing of Class I and Class II devices exempt from 510(k) requirements is available on the Medical Device Exemptions 510(k) and GMP Requirements website. General limitations to the exemptions are found in Title 21 of the Code of Federal Regulations (CFR) in sections 862.9 through 892.9. Additionally, the FDA may partially limit the exemption from 510(k) requirements to specific devices within a classification regulation. It is important to confirm a device's 510(k) exemption status and any limitations that may apply.

Other helpful resources include 21 CFR 862-892, the Product Classification database and the FDA's prior exemption announcements published in the Federal Register (for example, FDA-2017-N-1129). The Division of Industry and Consumer Education (DICE) within the FDA's Center for Devices and Radiological Health can also help you identify the appropriate requirements for your device.

Quality System Regulation/Good Manufacturing Practices Exemptions

All medical devices are subject to the Quality System Regulation (21 CFR 820), also referred to as the "Current Good Manufacturing Practices" or "Good Manufacturing Practices," unless there is an exception or exemption noted in 21 CFR 820. Regardless of the Class, you should refer to the device's specific classification regulation to confirm regulatory requirements.

Humanitarian Device Exemption

The Humanitarian Device Exemption (HDE) Program creates a new regulatory pathway for humanitarian use devices (HUD) intended for diseases or conditions that affect small (rare) populations in the U.S. The regulation provides for the submission of a humanitarian device exemption (HDE) application, which is similar in both form and content to a PMA application but is exempt from the effectiveness requirements of a PMA.

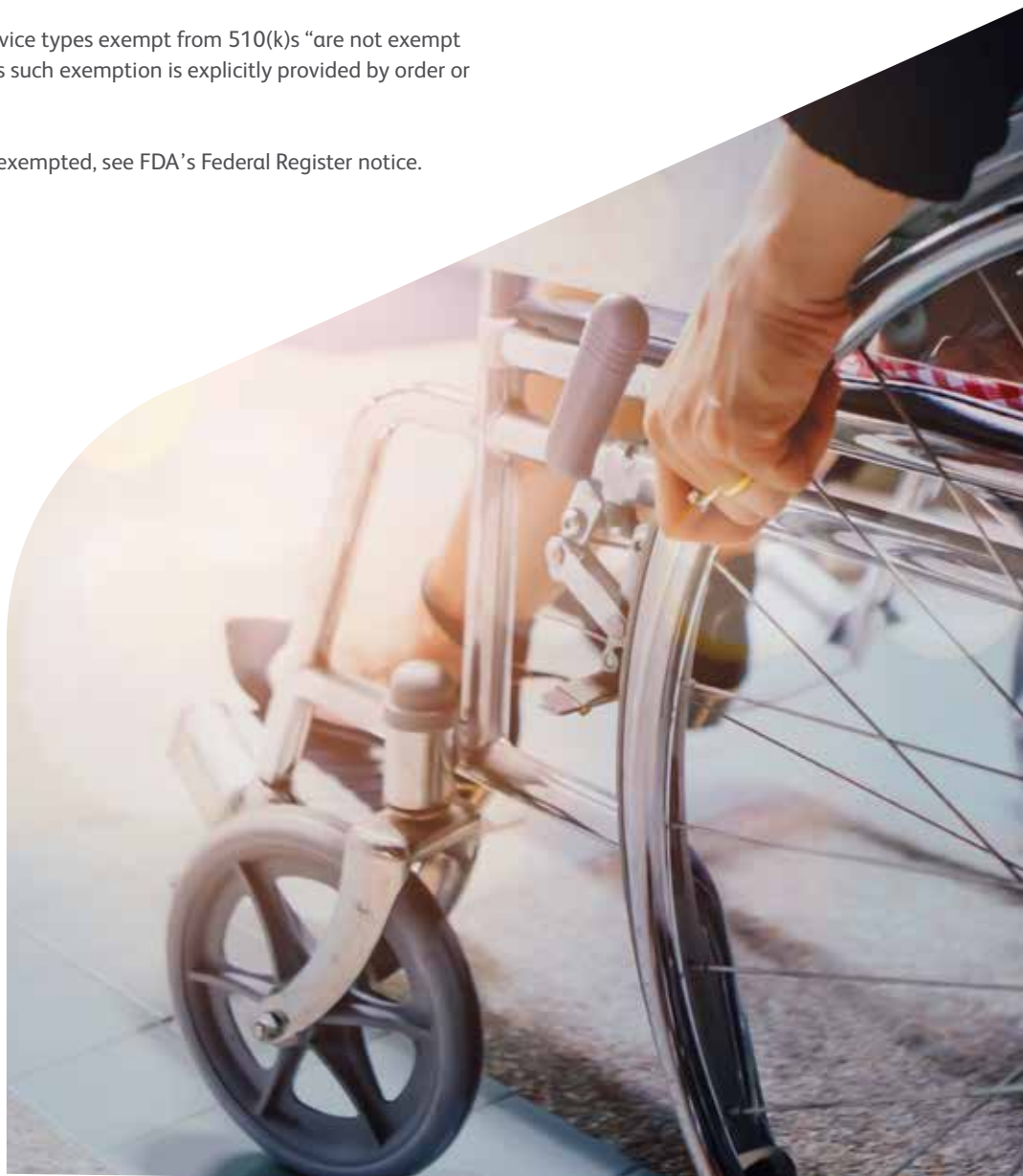
An approved HDE authorizes marketing of the HUD. However, a HUD may only be used in facilities that have established a local institutional review board (IRB) to supervise clinical testing of devices and after an IRB has approved the use of the device to treat or diagnose the specific disease. The labelling for a HUD must state that the device is a humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated.

Recent updates to exemptions

In July 2019, the FDA finalized a list of 1,003 types of class II medical devices that the agency believes do not present risks that require premarket notification review to provide a reasonable assurance of safety and effectiveness. The FDA also previously identified more than 70 class I devices that are now exempt from 510(k) requirements.

However, the FDA also noted that device types exempt from 510(k)s "are not exempt from other regulatory controls, unless such exemption is explicitly provided by order or regulation."

For the complete final list of devices exempted, see FDA's Federal Register notice.



Medical device reporting (MDR)

On November 8, 2016, the FDA issued the long-awaited final guidance, “Medical Device Reporting for Manufacturers. The final guidance addresses medical device reporting and recordkeeping requirements for device-related adverse events and certain types of device malfunctions. The guidance supersedes the 2013 draft guidance, as well as the 1997 MDR guidance document.

The final guidance provides clarification on several key issues related to MDR by breaking them down into a question and answer format and including helpful examples to make clear their position. Some areas highlighted by the FDA as key issues are:

- When a firm “becomes aware” that an MDR reportable event has occurred.
- MDR submission rules involving a marketed device studied under an investigational device exemption (IDE).
- MDR submission rules involving adverse events that occur outside the U.S..
- Exemption request process for MDR reporting for a contract manufacturer
- Clarification of the submission of 5-day reports and remedial actions.
- Clarification on the 2-year presumption for reportable malfunctions.

Now that the final guidance document has been published, manufacturers of medical devices may need to review and revise their reporting procedures where necessary.

Medical device user fees

The federal law authorizes the FDA to charge a fee for a medical device product review. Under the user fee system, medical device companies pay fees to the FDA when they register their establishments and list their devices with the agency, whenever they submit an application or a notification to market a new medical device in the U.S. and for certain other types of submissions.

The fees for the fiscal year 2020 (October 1, 2019, through September 30, 2020) are as follows:

Application type	Regulation Citation	Small Business Fee +
510(K)ǂ	$11,594	$2,899
513(g)	$4,603	$2,302
PMA, PDP, PMR, BLA	$340,995	$85,249
De Novo Classification Request	$102,299	$25,575
Panel-track supplement	$255,747	$63,937
180-Day Supplement	$51,149	$12,787
Real-Time Supplement	$23,870	$5,968
BLA Efficacy Supplement	$340,995	$85,249
30-Day Notice	$5,456	$2,728
Annual fee for periodic Reporting on a class IIII deivce (PMAs, PDFs, and PMRs)	$11,935	$2,984

+ For small businesses with an approved SBD.
ǂ Note: all types of 510(k)s (Traditional, Abbreviated, and Special) are subject to the user fee. However, there is no user fee for 510(k)s submitted to the FDA on behalf of an FDA-accredited third-party reviewer.

For more detailed information about medical device classification & marketing in the U.S., visit www.fda.gov.

Reference list:

https://www.fda.gov/medical-devices
https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance
https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device
https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-ii-exemptions
https://www.fda.gov/medical-devices/medical-device-safety
https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa
https://bbacro.com/new-fda-guidance-medical-device-reporting-manufacturers/
https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2017/7/fda-finalizes-list-of-1,003-class-ii-device-types-exempt-from-510(k)-requirements

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The **Florida International Medical Expo (FIME)**, brings together the U.S. and Latin American healthcare community, which is increasingly interested in figuring out how to best navigate the complex process that is working with the FDA, to bring innovative products to market.

This summary provides you the first information you need to help your company expand into the United States, and we hope it was insightful and of value.

We look forward to seeing you at FIME 2020, taking place **New dates:** August 25-27, 2020, at the Miami Beach Convention Center, to continue learning and networking with peers facing the same challenges you face and who are equally looking to expand their business across the Americas.

For more information, visit **fimeshow.com**