

Here then, are the differences between the different medical device classes:

Class I Medical Devices

A Class I medical device are those devices that have a low to moderate risk to the patient and/or user. Today, 47% of medical devices fall under this category and 95% of these are exempt from the regulatory process. If a device falls into a generic category of exempted Class I devices, a premarket notification application and FDA clearance is not required before marketing the device in the U.S. However, the manufacturer is required to register their establishment and list their generic product with FDA. Examples include enema kits, elastic bandages, manual stethoscopes, and bedpans.

Class II Medical Devices

Class II medical devices are those devices that have a moderate to high risk to the patient and/or user. 43% of medical devices fall under this category. Most medical devices are considered Class II devices. Examples of Class II devices include powered wheelchairs and some pregnancy test kits.

Class III Medical Devices

Class III medical devices are those devices that have a high risk to the patient and/or user. These devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. They represent 10% of medical devices regulated by the FDA. Examples of Class III devices include implantable pacemakers and breast implants.

We hope this was helpful. BMP Medical is an FDA approved original equipment manufacturer of medical devices. In order to ensure approval, as part of our validation services, we advise and assist clients in helping them understand the distinctions between the different medical device classifications.