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You may ask yourself what is a medical device class and what's the difference between class I, II and III. The answer, in simple terms, is medical devices are categorized by class for the purpose of informing patients, doctors and manufacturers the amount of risk involved and the intention for the medical device. At Litron we specialize in the manufacturing and assembly of Class II and III medical devices.

Classification of Medical Devices

A medical device is designed to improve patient's health in diagnosis, therapy or surgery which are monitored and under strict regulations by the food and drug administration, FDA.¹ Medical devices are classified into three classes based on the US classification system, which defines the amount of risk involved with the medical device and proper procedures that must be followed when using and manufacturing the device.

What Is a Class I Medical Device?

Class I Medical Devices are simple in design and have little to no potential risk. Medical devices classified as type I must follow general FDA policy which includes registering the medical device, proper branding and labeling, proper manufacturing techniques and the FDA must be notified prior to marketing the device. Class I Medical Devices include tongue depressors, elastic bandages, hand held dental instruments and examination gloves.

What Is a Class II Medical Device?

Class II Medical devices are more complicated in design and pose a minimal risk. Medical devices classified as type II must follow general policy and special labeling, mandatory performance standards and post market surveillance. Most medical devices fall into the Class II medical devices category such as X-ray machines, powered wheelchairs, infusion pump and surgical and acupuncture needles.²

What Is a Class III Medical Device?

Class III Medical Devices are intricate in design and have the strictest guidelines because they pose the greatest risk. Class III Medical Devices must follow Class I and Class II guidelines but must also be pre-market approved by the FDA and a scientific review of the medical device must be made prior to marketing. Class III medical devices support or sustain human lives therefore malfunction is absolutely unacceptable. Class III Medical Devices include implanted pacemakers, heart valves and implanted cerebral simulators.

Medical Device Specialists

Litron specializes in Class II and III medical devices and owns a Class 10k cleanroom to ensure proper quality and control. Litron's cleanroom controls humidity, particles in the air and electrostatic discharge all of which are vital components that will affect the medical device. Litron machines, welds and seals the highest quality, precision components for the medical industry and no matter the quantity, Litron can handle a single prototype run to several hundreds or thousands of parts.

¹ Information sourced from http://en.wikipedia.org/wiki/Medical_device

² Information sourced from <http://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/ucm142523.htm>



To find out more about Litron and how we can facilitate your next medical project contact us today!