

to different levels of regulations and norms, i.e., stringent regulations for higher class of medical devices:

Class I: This class includes medical devices that pose minimum risk to a patient and are simpler in design as compared to Class II and Class III medical devices. Class I devices are classified in the ‘general controls’ category, as specified by the US FDA, and include devices such as tongue depressors, bedpans, elastic bandages, examination gloves, hand-held surgical instruments and X-ray film. The manufacturing and distribution of medical device products in this class generally requires:

Class II: According to the US FDA, Class II devices are subject to ‘special controls’ in addition to ‘general controls’. These devices require a higher level of safety assurance in terms of potential injury or other harm to the patient. Devices in this class include X-ray machines, powered wheelchairs, infusion pumps, surgical drapes and ultrasonic diagnostic devices. In addition to Class I requirements, the manufacturing and distribution of medical device products in this class generally entails the following:

- Special labeling requirements
- Compliance with performance standards
- Post-market surveillance
- Pre-market approval may be required

Class III: Devices in this class require the highest level of safety and effectiveness assurance as the potential threat to the patient is highest in their case. Information availability regarding the safety aspect of these devices is generally limited as compared to Class I and Class II devices; and these, therefore, require additional safety measures after ‘general controls’ and ‘special controls’. Medical devices in this category include life-supporting or life-sustaining devices, such as replacement heart valves, implanted cerebellar stimulators, implantable pacemaker pulse generators, endoscopic (intra-bone) implants, etc. In addition to Class I and Class II requirements, the manufacture and supply of these devices entails the following:

- A scientific review to ensure the safety and effectiveness of a device
- Pre-market approval (mandatory)

In some countries, a device-tracking system to maintain and update information about the recipients of the device is necessary for certain Class III devices such as implantable pacemakers.

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