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Short Communication

Medical Devices and their Classification

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DESCRIPTION

Marketing of medical devices around the world, it's difficult to come up with a universal definition. Despite the fact that various agencies frequently communicate and debate the definition in general, slight variances in phrasing prohibit global harmonization of the concept of a medical device; hence the appropriate definition of a medical device varies by location [1-4].

Because the regulatory criteria for medical devices and medicines differ, a section of the definition of a medical device is frequently used to distinguish between them. In vitro diagnostics are frequently recognized as a subtype of medical devices, and accessories are frequently defined as medical devices. Any gadget that is meant to be used for medical reasons is referred to as a medical device.

When employing a device for medical reasons, there is a significant risk of harm, hence medical devices must be shown safe and effective with reasonable assurance before regulating governments allow the device to be marketed in their country.

Simple, low-risk devices like tongue depressors, medical thermometers, disposable gloves, and bedpans are examples, as are complicated, high-risk devices that are implanted and keep people alive. Pacemakers, which aid in the conduct of medical diagnostics, implants, and prosthesis, are an example of high-risk devices with embedded software. Medical device design is a significant part of the discipline of biomedical engineering.

Medical device classification based on risk is critical for protecting patient and staff safety while also facilitating medical product marketing. Lower risk devices, such as a stethoscope or tongue depressor, are not required to undergo the same level of testing as higher risk devices, such as artificial pacemakers, thanks to the establishment of separate risk classifications. Using a risk classification hierarchy helps regulatory agencies to be more flexible when examining medical devices.

Non-invasive, everyday gadgets or equipment are classified as Class I devices. Bandages, compression hosiery, and walking aids are examples of low-risk Class I devices. All that is required of such devices is that the maker completes a Technical File.

Class I devices

Class I devices are comparable to Class I equipment in that they are non-invasive, but they also contain sterile devices. Stethoscopes, examination gloves, colostomy bags, and oxygen masks are examples of Class Is devices. These devices also require a technical dossier, as well as an application to a European Notified Body for manufacture certification in accordance with sterility regulations.

Class Im devices

These are primarily low-risk measuring instruments. Thermometers, droppers, and non-invasive blood pressure measurement devices are all included in this category. Once again, the manufacturer must provide a technical file and be approved for manufacturing in compliance with metrology requirements by a European Notified Body.

Class IIa devices

Class IIa devices pose a low to moderate risk and are mostly used to implant devices into the body for a short period of time. Class IIa devices are those that are only implanted in the body for 60 minutes to 30 days. Hearing aids, blood transfusion tubes, and catheters are just a few examples. Technical files and a compliance test performed by a European Notified Body are among the requirements.

Class IIb devices

Slightly more complicated than class IIa devices, class IIb devices pose a medium to high risk and are frequently implanted in the body for 30 days or more. Ventilators and intensive care monitoring equipment are two examples. Identical compliance path for Class IIa devices, with the addition of a Notified Body device type inspection.

Class III gadgets

Class III devices are considered to be extremely dangerous. Balloon catheters, prosthetic heart valves, pacemakers, and other medical devices are examples. A comprehensive quality assurance

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system audit, as well as a European Notified Body review of both the device's design and the device itself, is all required for approval. A Declaration of Conformity ensures that medical equipment is approved. This declaration is provided by the manufacturer, but it must be validated by a Certificate of Conformity issued by a Notified Body for products in Classes Is, Im, Ir, IIa, IIb, or III.

The Swiss Federal Administrative Court ruled in November 2018 that the "Sympto" app, which analyses a woman's menstrual cycle, is a medical device because it estimates a fertility window for each woman based on specific information. Sympto-Therm Foundation, the producer, said that this was a didactic rather than a medical procedure.

CONCLUSION

Medical device production necessitates a certain level of process control, depending on the device's categorization. There are more controls when there is a higher risk. Manufacturers are already beginning to plan for manufacturability while still in the R&D phase. This means that items can be more precisely engineered for manufacturing, resulting in shorter lead times, tighter tolerances, more enhanced specs and prototypes. Work is now faster with the aid of CAD or modeling platforms, and this may also be used as a tool for strategic design generation as well as a marketing tool. Failure to fulfill cost targets will result in significant losses for a company. Furthermore, given worldwide rivalry, medical device manufacturers must not only research and develop innovative products, but they must do so urgently.

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