

Medical Device FAQ

What is a Medical Device?

Basically a device is an object that its intended use is not achieved through chemical action or by being metabolized by the body.

A device is defined in the Act as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or condition and/or intended to affect the structure or any function of the body which does not achieve its intended use through chemical action and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

What is an IDE?

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification (510(k)) submission to FDA.

What is a PMA?

Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. PMA is the most stringent type of device marketing application required by FDA.

What is a Humanitarian Use Device (HUD)?

Is a device that is intended to benefit patients in the treatment and diagnosis of diseases and conditions that affect or is manifested in fewer than 4,00 individuals in the United States per year.

What is a Humanitarian Device Exemption (HDE)?

Is the application to the FDA where you request that your device is exempt from the effectiveness requirements under the regulations. If the FDA approves your HDE request then you are authorized to market your Humanitarian Use device (HUD).

What are “special controls”?

Special Controls can be almost anything deemed necessary by FDA’s Center for Devices and Radiologic Health (CDRH). Special controls may include special labeling requirements, mandatory performance standards and post-market surveillance. Special controls are carefully detailed by CDRH and made available to all interested parties.

Premarket approval (PMA) is the FDA’s process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. PMA is the most stringent type of device marketing application required by the FDA. To gain approval, the manufacturer must present adequate scientific evidence to assure that the device is safe and effective for its intended use.

Who Must Apply for an IDE?

The sponsor of the clinical trial is responsible for submitting the IDE application to FDA (§812.40) and obtaining Institutional Review Board (IRB) approval before the study can begin.

When to Apply?

Study approval must be obtained PRIOR to enrolling patients at the study site. Each site must have approval from the reviewing IRB for that site prior to beginning the study. For significant risk device studies, in addition to IRB approvals, the sponsor must also have an approved IDE from FDA prior to beginning the study at any site. The reviews of applications to FDA and to the IRBs are independent and, therefore, may be submitted simultaneously.

Significant Risk Device

A significant risk device presents a potential for serious risk to the health, safety, or welfare of a subject. Examples include sutures, cardiac pacemakers, hydrocephalus shunts, and orthopedic implants.

Non-Significant Risk Devices

Non-significant risk devices are devices that do not pose a significant risk to the human subjects. Examples include most daily-wear contact lenses and lens solutions, dental tools, and catheters.

Which devices are exempt for regulatory review by the FDA?

Devices that are sufficiently well-known, and their safety and effectiveness are sufficiently well characterized and established do not require review by the FDA. They are still subject to general requirements that proper labeling, manufacture and investigation of adverse events.

What is a predicate device?

The legally marketed device(s) to which equivalence is drawn is known as the predicate device(s).

What substantially equivalent mean?

A 510(k) requires demonstration of substantial equivalence to another legally U.S. marketed device. Substantial equivalence means that the new device is at least safe and effective as the predicate.

Which devices are Class I devices?

Class I device are subject to the least regulatory control, called “general controls”. They present minimal potential for harm to the user. Most class I devices are exempt from PMA and/or good manufacturing practices regulation. Examples of Class I devices are elastic bandages, examination gloves, and hand-held surgical instruments.

Which devices are Class II devices?

Class II devices are those for which “general controls” alone are insufficient to assure safety and effectiveness. Special controls may include special labeling requirements, mandatory performance standards and postmarket surveillance. Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes.

Which devices are Class III devices?

Class III is the most stringent regulatory category for devices. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls. Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Examples of class III devices are implantable pacemaker pulse generators and intra-bone dental implants.

FDA Guidance on IDE Policies and Procedures:

<http://www.fda.gov/cdrh/ode/idepolicy.html>