ADVARRA

US Medical Device Regulation 101

Speed the IRB review process by understanding how medical devices are classified and what the IRB must review to approve device research.

What Is a Medical Device?

A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

- Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes

(21 U.S.C. 321(h))

Devices in the Marketplace: Characteristics by Class

Regulatory Status	Class I	Class II	Class III
Characteristics and Risk	Lowest risk, simple in design	Moderate risk	High risk
Most Likely Regulatory Pathway	510(k) exempt	510(k) clearance	PMA approval
Examples	Prescription sunglasses, elastic bandages, hand splint, pharmacy app displaying information on drug cost, risks, and potential interactions	Powered/adjustable hospital bed, pulse oximeter, feeding tube, TENS unit, app connecting a spirometer to a smartphone	Implants (hip, knee, breast), robotic surgical devices, cardiac pacemaker, software for ophthalmic use, smartphone app controlling an insulin pump
IRB Review Required?	Maybe*	Yes	Yes

*Some Class I, 510(k) exempt medical devices do not require testing in human subjects/IRB review before the product can be marketed. However, manufacturers making safety or effectiveness claims in device packaging or advertising materials should conduct studies in human subjects with IRB approval to support those marketing claims.

IRB Review of Device Studies

IDE Exempt Investigations: Studies Not Requiring an SR/NSR Determination

Eligible Studies

- FDA cleared (510(k)) or approved (PMA) devices used on label
- Noninvasive diagnostic devices not requiring an invasive sampling procedure, not introducing energy into a subject, and not used for purposes of diagnosis without confirmation by a medically established diagnostic product or procedure
- Devices undergoing consumer preference testing, testing of a modification, or testing in combination with another device in commercial distribution so long as the testing is not to establish safety or efficacy and does not place subjects at risk

Provide to the IRB

- Protocol and consent form(s)
- Documentation from FDA if applicable (510(k), PMA, FDA determination of device status)
- Instructions for use, user manuals(s), investigator's brochure, other official device documentation, and/or a comprehensive description of the device

Studies of Significant Risk and Nonsignificant Risk Medical Devices

Device Status	Significant Risk	Nonsignificant Risk
Definition	• Intended as an implant, • Used in supporting or sustaining human life, • For a substantial importance in diagnosing, curing, mitigating or treating disease, OR • Presents a potential for serious risk to subject	A device which does not meet the definition of a significant risk device
Before a Study May Begin	IDE approval from FDA IRB approval of the study	IRB approval of the study
Example	Investigational cardiac valve, investigational assay used to determine eligibility for participation in some clinical trials	Investigational wearable biometric monitor and accompanying mobile app
Provide to the IRB	• IDE number or FDA IDE letter • Protocol and consent form(s) • Documentation from FDA if applicable (510(k), PMA, FDA determination of device status) • Instructions for use, user manual(s), investigator's brochure, other official device documentation and/as available or a comprehensive description of the device	• Sponsor's/investigator's rationale in support of an NSR determination • Protocol and consent form(s) • Documentation from FDA if applicable (510(k), PMA, FDA determination of device status) • Instructions for use, user manual(s), investigators brochure, other official device documentation, and/or a comprehensive description of the device

Definitions

510(k): A premarket submission made to FDA to demonstrate the device to be marketed is as safe and effective (i.e., substantially equivalent) to a legally marketed device that is not subject to premarket approval (PMA) requirements

IDE: Investigational device exemption; FDA authorization allowing a device manufacturer to ship the investigational device for the purposes of clinical research (as regulated in 21 CFR 812)

IDE Exempt: A device study that is exempt from IDE regulations by virtue of the criteria listed in 21 CFR 812.2 (c)

PMA: Premarket approval; the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices

Device regulations can be tricky. Need more information?

Contact BusinessDevelopment@advarra.com to be connected with our device experts