IRBs and Researchers: Know Your U.S. Medical Device Documentation

Complex regulatory documentation can slow down the IRB review of medical devices. However, researchers and IRBs can speed things up with a shared understanding of how medical devices are classified and which documents the IRB must review to confirm the device's regulatory status.

Regulatory Status

Not Eligible for Marketing (i.e. Cannot be Sold) in the U.S.

Does it have an investigational device exemption (IDE)?

IDE — FDA determined that the research proposed in the IDE application can proceed

Typically intermediate to high-risk e.g. cochlear implants

IRB must: Confirm that IDE is in place and research as proposed in the protocol can proceed

Is the device exempt?

Exempt — Exempt from needing an IDE because it is a diagnostic device†

Typically low-risk e.g. pregnancy test kits

IRB must: Confirm that the device is exempt from needing an IDE because it is a diagnostic device†

Is it a Non-Significant Risk (NSR) device?

NSR — The device as used in the study is not a significant risk device

Typically low-risk e.g. general biliary catheter

IRB must: Explicitly determine that the device, as used in the study, is not a significant risk device‡

Eligible for Marketing (i.e. Can be Sold) in the U.S.

Is it a Class I device?

Class 1 — Product category is within the lowest risk classification

Low-risk e.g. prescription sunglasses, elastic bandages, hand-held surgical instruments

IRB must: Confirm that the device is Class I

Does it have 510(k) Clearance?

510(k) — FDA determined that device is equivalent to a predicate device in use, safety, and effectiveness.

Intermediate-risk e.g. blood glucose test systems, arterial catheters, infusion pumps

IRB must: Confirm that the device as used in the study is being used according to its cleared indication(s)

Does it have pre-market approval?

PMA — FDA determined that the device is safe and effective.

High-risk e.g. implantable pacemaker, HIV diagnostic tests

IRB must: Confirm that the device as used in the study is being used according to its approved indication(s)

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, or
- 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))

†Diagnostic Device

- Is noninvasive
- Does not require an invasive sampling procedure that presents significant risk
- Does not by design or intention introduce energy into a subject
- Is not used without confirmation of the diagnosis by another medically established product or procedure

(21 CFR 812.2(c)(3))

‡Significant Risk Device

- Intended as an implant;
- Purported or represented to be for a use in supporting or sustaining human life;
- For a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health; or
- One that presents a potential for serious risk to the health, safety, or welfare of a subject

(21 CFR 812.3(m))

About Kinetiq

Kinetiq, a division of Quorum Review IRB, is a consulting and technology firm that delivers innovative solutions to the challenges of human subject protection and compliance in clinical research. We work with clinical researchers, research institutions, pharmaceutical, biotechnology and medical device companies as well as others around the world to develop contemporary approaches to a changing landscape.

Contact us at info@Kinetiqldeas.com to get started.

Need More Info?

Watch this **free on-demand webinar** presented by Quorum:

Reviewing Research Involving Medical Devices

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