

# 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.



## 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@KinetiqIdeas.com](mailto:info@KinetiqIdeas.com) to get started.

## Need More Info?

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**Reviewing Research Involving Medical Devices**

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