REBs and Researchers: Know Your Canadian Medical Device Documentation

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

Regulatory Status

Not Eligible for Marketing (i.e. Cannot be Sold) in Canada

Does the device have investigational testing authorization (ITA)?

ITA

Health Canada determined that the research proposed in the ITA application can proceed

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

REB must:

Confirm that ITA is in place and research as proposed in the protocol can proceed

Eligible for Marketing (i.e. Can be Sold) in Canada

Is it a Class I device?

Class 1

Product category is within the lowest risk classification

Low-risk
e.g. prescription sunglasses

REB must:

Confirm that the device is Class I

Is it licensed (i.e. approved)?

Licensed

Health Canada reviewed a medical device license (MDL) application and approved it

Note: *This application process is similar to the FDA 510(k) for intermediate-risk and intermediate to high-risk devices, and similar to the FDA PMA for high-risk devices*

Intermediate-risk
e.g. blood reinfusion bags

Intermediate to high-risk
e.g. orthopedic implants

High-risk
e.g. implantable pacemakers

REB must:

Confirm that the device as used in the study is being used according to its licensed use

What is a Medical Device?

an instrument, apparatus, contrivance or other similar article, or an in vitro reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in

(a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,

(b) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals,

(c) diagnosing pregnancy in human beings or animals,

(d) caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or

(e) preventing conception in human beings or animals;

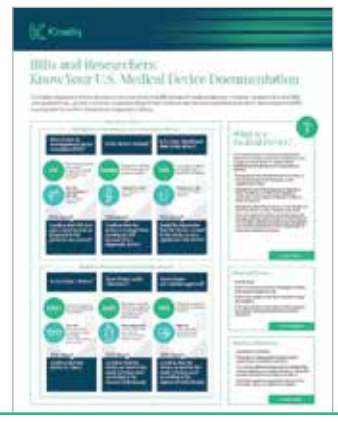
*Section 2 of the Canadian Food and Drugs Act

Device Classes

- **Class I: Low-risk devices**
- **Class II: Intermediate-risk devices**
- **Class III: Intermediate-risk to high-risk devices**
- **Class IV: High-risk devices**

How Does Documentation Differ in the U.S?

Check out our infographic outlining U.S. medical device documentation at bit.ly/usdevices



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 to get started.

Still Need More Info?

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

Reviewing Research Involving Medical Devices

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