ADVARRA

Canadian Medical Device Regulation 101

Speed the research ethics board (REB) review process by understanding how medical devices are classified and what the REB must review to confirm a device's regulatory status

What is a Medical Device?

A medical device is 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

(e) Preventing conception in human beings or animals

However, it does not include such an instrument, apparatus, contrivance, or article, or a component, part or accessory of any of them, that does any of the actions referred to in [the list above] solely by pharmacological, immunological, or metabolic means or solely by chemical means in or on the body of a human being or animal.

Section 2 of the Canadian Food and Drugs Act

REB Review of Device Studies

Ineligible for marketing in Canada (i.e., cannot be sold)

Regulatory designation	Investigational testing authorization (ITA)
Designation explanation	Health Canada determined the research proposed in the ITA application can proceed Required for research involving Classes II, III, and IV devices
Typical risk	Intermediate to high
Example	Cochlear implants
REB required actions	Confirm an ITA has been or will be obtained before the research will begin

Eligible for marketing in Canada (i.e., can be sold)

Regulatory designation	Class I	Licensed (e.g., approved)		
Designation explanation	Product category is within the lowest risk classification ITA not required for Class I devices	Health Canada reviewed a medical device license (MDL) application and approved it*		
Typical Risk	Low	Intermediate	Intermediate to high	High
Example	Prescription sunglasses	Blood reinfusion bags	Orthopedic implants	Implantable pacemakers
REB Required Actions	Confirm that the device is Class I	Confirm that the device as used in the study is being used according to its licensed use		

* This application process is similar to the FDA 510(k) for intermediate-risk and intermediate to high-risk devices, and similar to the FDA pre-market approval (PMA) for high-risk devices.

Devices in the Marketplace

Characteristics by Class

Class I: Low-risk devices

Class II: Intermediate-risk devices

Class III: Intermediate-risk to high-risk devices

Class IV: High-risk devices

Note: Health Canada provides 16 rules to assist in determining a device's classification. For details, see Health Canada Guidance on the Risk-Based Classification System for Non-In Vitro Diagnostic Devices (Non-IVDDs).

Device regulations can be tricky. Need more information?

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