

# 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)	<b>Regulatory designation</b>	Investigational testing authorization (ITA)			
	<b>Designation explanation</b>	Health Canada determined the research proposed in the ITA application can proceed  Required for research involving Classes II, III, and IV devices			
	<b>Typical risk</b>	Intermediate to high			
	<b>Example</b>	Cochlear implants			
	<b>REB required actions</b>	Confirm an ITA has been or will be obtained before the research will begin			
Eligible for marketing in Canada (i.e., can be sold)	<b>Regulatory designation</b>	Class I	Licensed (e.g., approved)		
	<b>Designation explanation</b>	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*		
	<b>Typical Risk</b>	Low	Intermediate	Intermediate to high	High
	<b>Example</b>	Prescription sunglasses	Blood reinfusion bags	Orthopedic implants	Implantable pacemakers
	<b>REB Required Actions</b>	Confirm that the device is Class I	Confirm that the device as used in the study is being used according to its licensed use		

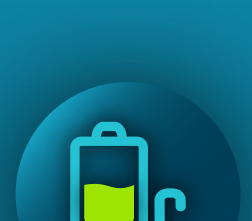
\* This application process is similar to the FDA 510(k) for intermediate-risk and intermediate to high-risk devices, and similar to the FDA pre-market approval (PMA) for high-risk devices.

## 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](mailto:BusinessDevelopment@advarra.com) to be connected with our device experts