

Investigational Testing Requirements

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Special Control Sales

- The *Regulations* allow for two instances in which a medical device may be authorized for sale when it has not met the general Safety and Effectiveness requirements.
 - Special Access (Part 2 of the *Regulations*)
 - Investigational Testing (Part 3)

Authorizations Under Part 2 of the Regulations

- Sale is exempt from the safety, effectiveness and quality provisions of Part 1 of the Regulations.
- However, manufacturers are obliged to meet:
 - specific labeling requirements;
 - maintain adequate distribution records;
 - mandatory problem reporting of serious adverse events within 72 hours; and,
 - implant registration if applicable (Section 66).

Authorizations Under Part 2 of the Regulations

- Authorizations are required for Class III and IV custom-made medical devices.
- All devices intended for special access require an authorization prior to importation and sale in Canada.



Part 2 – Custom-made Devices

- Custom-made devices other than a mass-produced medical device, must:
 - be manufactured in accordance with written instructions from a health care professional;
 - differ from devices generally available from a dispenser; and,
 - be for the sole use of a particular patient or professional.

Part 2 - Special Access

- A special access authorization is a means to provide access to medical devices for emergency use or if conventional therapies have failed, are unavailable or are unsuitable.

Part 3 - Investigational Testing

- Grants the authorization to conduct clinical trials involving human subjects in Canada.
- Allows manufacturers to acquire evidence of effectiveness as required by Section 12 (Part 1) of the Regulations.
- Is applicable to *in vitro* diagnostic devices when:
 - effectiveness has not been adequately established for clinical use; or,
 - additional evidence of safety and effectiveness can only be obtained using target populations.

Part 3 - Investigational Testing

- Applications are received from the manufacturer for Class II, III and IV medical devices.
- For Class I medical devices no application is required but manufacturers or an importer must possess all of the information applicable to a Class II application.
- Authorization for sale is granted to the manufacturer.

Investigational Testing Requirements (1)

- Introduction:
 - Device description;
 - Design philosophy, and;
 - Marketing history.
- Risk assessment and risk reduction measures:
 - Previous studies;
 - Alternative treatment options, and;
 - Known precautions, warnings, etc.

Investigational Testing Requirements (2)

- Name and address of the institution(s) involved.
- Study Protocol
- Labelling, with required restrictions.
- Additional requirements for Class III and IV applications:
 - Names and curriculum vitae of the principal investigator(s)
 - IRB or ethics committee approval(s)
 - Signed investigator agreements

The Study Protocol

- Must consider, as appropriate the following:
 - Objective – hypothesis is clearly stated;
 - Subject selection criteria for inclusion and/or exclusion;
 - Number of subjects must be statistically significant;
 - The diagnostic methods must be clearly identified;
 - Criteria for determining success and/or failures must be defined;
 - A valid control group must be included, and;
 - A copy of the patient consent form and/or material must be provided.

Investigational Device Labelling

- Provide the manufacturer name and address
- Identify the device by name
- Contain the following statements, as appropriate in both English and French:
 - “Investigational Device – To be used by qualified investigators only”
 - For IVDDs “The performance specifications of this product have not been established”

Health Canada's Review Process

- The review process for investigational testing applications involves a review of the information provided against the following criteria for acceptability:
 - can the device be used safely, and;
 - can the testing objectives be achieved by following the protocol?

Potential Review Outcomes

- Request additional information
- Authorization for investigational testing, specific to:
 - Investigator's Name
 - Type of diagnosis/treatment
 - Number of units to be sold
 - Protocol identification
- An authorization will not be issued if it is determined:
 - Device not safe
 - Not in best interests of patients
 - Objective cannot be achieved

Post-authorization Responsibilities

- Compliance with interim reporting requirements.
- Mandatory problem reporting, in this case within 72 hours to the Bureau.
- Complaint handling, distribution records and recalls.
- Implant registration (if applicable).

Advertising of Medical Devices Under Investigational Testing

- The advertiser must hold an investigational testing authorization for the device in question.
- The advertisement must clearly state:
 - That the device is the subject of investigational testing, and;
 - The purpose for which the device is being tested.

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