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Process for Submitting Approval Applications to Health Canada for Medical Devices

Introduction

Assess the need for a consultation meeting

Build the application package

Submission to Health Canada

Review by Health Canada

Step 1

- The manufacturer or importer must submit an Investigational Testing Authorization (ITA) for any unlicensed Class II, III, or IV medical device imported or sold in Canada for testing on human subjects. If a protocol includes multiple unlicensed devices from different manufacturers, each manufacturer must submit a separate ITA application.
- The guidance provided is based on Health Canada's Guidance Document: Applications for Investigational Testing Authorization for Medical Devices.
- A Medical Device Classification Tool is available to help you determine the device class.

Step 2

- Although general questions can be addressed by email or phone, Health Canada encourages the manufacturer or importer to request a pre-ITA **consultation meeting** for more detailed guidance, especially when the investigation involves new Class III or IV devices or combination products.
- This meeting provides an opportunity to present relevant data, discuss product development concerns, and receive Health Canada's advice on gaps or issues related to the investigation. Researchers involved in the study may also participate.

For more information

See section 2.2 of the Guidance Document: *« Applications for Investigational Testing Authorization for Medical Devices »*.

Step 3

- The ITA application must be submitted in an "electronic format other than eCTD" and organized according to the current electronic document specifications. Health Canada provides the Guidance Document – Preparation of Regulatory Activities in Non-eCTD Electronic Format upon request only. Requests can be sent by email to no-reply.ereview.non-reponse@hc-sc.gc.ca and must include "Non-eCTD Guidance Document" in the subject line.
- The structure of the investigational testing application package and a summary of its content are described in Appendix 4 of the Guidance Document. Section 2.3.5 of the "Guidance Document: Applications for Investigational Testing Authorization for Medical Devices" includes Table 1, which lists the requirements for ITA applications based on the different device classes.

Step 4

- Combine all application components into a single ZIP file.
- Send this file by email to the Medical Devices Bureau, Therapeutic Products Directorate at: devicelicensing-homologationinstruments@hc-sc.gc.ca.
- If the file size exceeds 20 megabytes, it must be sent on an electronic medium (CD/DVD/USB) by mail to the address indicated in Appendix 1 of the guidance document.

Step 5

- The review process for ITA applications begins with a preliminary step to verify the completeness of submissions. If the information is complete, a notice of acceptance is issued. Otherwise, a notice of deficiency is sent, and the manufacturer or importer has 15 calendar days to provide the missing information; if not, the application will be rejected and a new submission will be required.
- The review of new applications or ITA amendments (excluding combination products) is completed within 30 calendar days from the start of the preliminary review or from receipt of a complete application after a deficiency notice. Minor amendments are processed within 15 calendar days. These timelines are targets and do not imply implicit authorization.
- Health Canada may request additional information if required elements are missing. The manufacturer or importer then has 60 calendar days to respond, after which Health Canada reviews the responses within 30 calendar days.
- If no response is received, the application may be withdrawn and resubmitted within 6 months. After this period, a new application will be required. Applications left unanswered after 60 calendar days may be rejected unless an extension is granted.
- When the information is deemed satisfactory, Health Canada issues an authorization or a revised authorization.
- A notice of refusal may be issued, even for a complete application, in the following cases (an appeal is possible):
  - The device cannot be used safely for investigational testing purposes.
  - The investigational testing is contrary to the best interests of patients.
  - The evidence does not demonstrate that the intended objective of the investigation is achievable.