Health Canada Santé Canada

Safe Medical Devices in Canada

What is a "medical device"?

The term "medical device" covers a wide range of products used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition. Some examples include pacemakers, artificial heart valves, hip implants, synthetic skin, medical laboratory diagnostic instruments, test kits for diagnosis and contraceptive devices.

Who regulates medical devices in Canada?

The Medical Devices Bureau of the Therapeutic Products Directorate (TPD) is the national authority that monitors and evaluates the safety, effectiveness and quality of diagnostic and therapeutic medical devices in Canada.

How does TPD regulate medical devices?

TPD ensures, to the extent possible, the safety, effectiveness and quality of medical devices in Canada by a combination of pre-market review, post-approval surveillance and quality systems in the manufacturing process.

Does a manufacturer have to obtain authorization prior to selling a medical device?

In Canada, certain devices must have a Medical Device Licence before they can be sold. To determine which devices need a licence, all medical devices have been categorized based on the risk associated with their use. This approach means that all medical devices are grouped into four classes with Class I devices presenting the lowest potential risk (e.g. a thermometer) and Class IV devices presenting the greatest potential risk (e.g. pacemakers).

Prior to selling a device in Canada, manufacturers of Class II, III and IV devices must obtain a Medical Device Licence. Although Class I devices do not require a licence, they are monitored through Establishment Licences.

What is an Establishment Licence?

An Establishment Licence permits importers, distributors, and manufacturers of Class I devices who do not sell their products through a licenced importer or distributor, to operate in Canada. Establishment Licencing ensures that TPD is aware of the identity of establishments that are selling or manufacturing devices. In addition, it requires establishments to provide assurance to TPD that regulatory requirements related to post-production activities have been met.

What are the steps in the review process for a medical device?

1. When a company decides that it would like to market a medical device in Canada, it submits a Medical Device Licence Application. The amount of information which must be submitted varies depending on the class of the device.
2. TPD reviews the application.
3. If the information provided meets the requirements of the Medical Devices Regulations, a licence is issued..

What happens if a medical device is not approved?

If TPD decides not to issue a Medical Device Licence, the manufacturer has the opportunity to re-submit the application and supply additional information or to appeal TPD's decision.

How long does it take to review a medical device licence application?

Although the length of the review varies depending on the class of the device, Class III & IV licence applications have a target review time of 75 days and 90 days respectively, and Class II licence applications have a 15 calendar day target.

Can new medical devices be obtained prior to a licence being issued?

The Special Access Programme (SAP) allows doctors to gain access to medical devices that have not been licenced in Canada. The SAP is used in emergency situations or when conventional therapies have failed, are unavailable or are unsuitable to treat a patient. For further information on this topic, please refer to the fact sheet entitled, "Special Access Programme (medical devices)."

What happens after a medical device is licensed and on the market?

TPD plays a role in monitoring medical devices after they are licensed to ensure their continued safety and effectiveness. If a medical device is found to no longer be safe and effective, its licence can be suspended or the manufacturer may be requested to recall or refit the medical device.

For further information

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