Health Canada Santé Canada

Canada

Drugs and Health Products

Notice: Use of United States Food and Drug Administration (FDA) Guidance Materials to support Canadian Medical Devices Licence Applications

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Officials in the United States and Canada continue to work together to identify areas of mutual interest and benefit, including work on the Regulatory Cooperation Council.

By way of this Notice, Health Canada is formally communicating its position on the use of FDA guidance materials to guide safety and effectiveness considerations as a means to address premarket submission requirements for medical devices.

The FDA regularly publishes guidance documents that outline recommendations regarding the technical performance assessment data for a variety of medical devices that are useful to device manufacturers. Health Canada encourages manufacturers to reference FDA technical guidance documents on topics where no similar Health Canada guidance is available.

Please direct any questions or comments regarding the content of this Notice to the following:

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