Archived Content

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Notice

Our file number: 10-113407-66

To: All manufacturers of non-*in vitro* diagnostic Class III and IV Medical Devices who wish to submit an application for a Medical Device Licence.

Subject: Health Canada's Intention to Adopt the Use of the Summary Technical Documentation (STED) for non-*in vitro* diagnostic Class III and IV Premarket Medical Device Licence Applications.

Application

This notice affects:

- All manufacturers of non-*in vitro* diagnostic Class III and IV Medical Devices.

Context

On August 10, 2009, the Health Canada Medical Devices Bureau issued a notice proposing to fully implement the use of the STED for Class III and IV premarket Medical Device Licence applications by July 1, 2010. In order to implement the STED, the Medical Devices Bureau is developing new guidance document outlining Canadian regulatory submission requirements for Class III and IV medical device licence applications not covered by the STED. This new guidance document will replace the current guidance document entitled *Guidance for Manufacturers Preparing a Premarket Application Using the Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices*. There have been delays in providing a draft document for stakeholder consultation. In order to finalize the new guidance document and make other necessary preparations, Health Canada has decided to delay the full STED implementation to July 1, 2011.

In the interim, the Medical Devices Bureau will continue to accept Class III and IV premarket review documents in the current format, as well as new STED submissions.

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Additional Information

For additional information on Medical Device Licence Application Requirements, please contact the following:

Device Licensing
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