Health Canada Santé Canada

June 23, 2014

DRAFT NOTICE

Re: Unique Device Identification (UDI) System for Medical Devices in Canada

Health Canada has participated in international initiatives on the Unique Device Identification (UDI) System for medical devices over the past several years. A unique device identifier is a code provided in both human- and machine-readable formats that enables the rapid and definitive identification of products. In December 2013, the International Medical Device Regulators Forum (IMDRF) UDI Working Group finalized a guidance document which provided a high-level conceptual framework describing how a global UDI System should work.

Over the next year or two, Health Canada intends to develop guidance for manufacturers on the implementation of a Unique Device Identification (UDI) system for medical devices sold or imported in Canada. In order to minimize the regulatory burden on businesses, Health Canada will use the principles outlined in the IMDRF guidance document, Unique Device Identification (UDI) of Medical Devices, and is not complementing additional Canadian-specific requirements at this time.

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

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