

# Torys on Food and Drug Regulatory

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## Classifying Medical Device Software in Canada

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Health Canada has indicated that it plans to release an updated notice on classifying patient management software in the coming weeks, modifying the notice it released on August 31, 2009.<sup>1</sup> The previous notice outlined the approach taken by the Medical Devices Bureau of Health Canada to classify patient management software as either a Class I or a Class II medical device.


### Application of the Notice

The notice refers to “patient management software,” suggestive of software that manages patient health records (e.g., eHealth records); however, the notice is intended to apply to medical software using patient personal health information and/or patient data for reporting, monitoring or analysis. Medical imaging software or patient diagnosis software that is sold as stand-alone software – that is, not always sold as part of a licensed medical device – would be subject to this notice.

### Classifying Software as a Class I or Class II Medical Device

Software that reports previously recorded information and does not perform any kind of analysis or decision making is classified as a Class I Medical Device. This would include software that is used solely for archiving or viewing information or images and is not involved in the acquisition, manipulation or transfer of data. Software involved in the “transfer of data” refers to software that communicates with other software or devices using custom protocols.

Patient management software intended to analyze or interpret patient health information or data is classified as a Class II Medical Device. This would include software involved in data manipulation, data analysis, data editing, image generation, recording of measurements, graphing, flagging of results or performing calculations. Additionally, any workstation interfacing directly with an imaging generating, viewing or storage device is classified as a Class II medical device.

Health Canada’s updated notice is expected to give more clarity to the way the department will regulate patient management software, but is not expected to change the way in which patient management software is classified. 

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<sup>1</sup> A copy of the notice can be found [here](#).