US & CANADA: REGULATION AND GUIDELINES ON MEDICAL SOFTWARE AND APPS

OR

A MEDICAL DEVICE IS A MEDICAL DEVICE IS A MEDICAL DEVICE...

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Overview

1. Where is SW used with medical devices?
2. What makes something a medical device?
3. Health Canada
4. US FDA

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WHERE IS SW USED WITH MEDICAL DEVICES?

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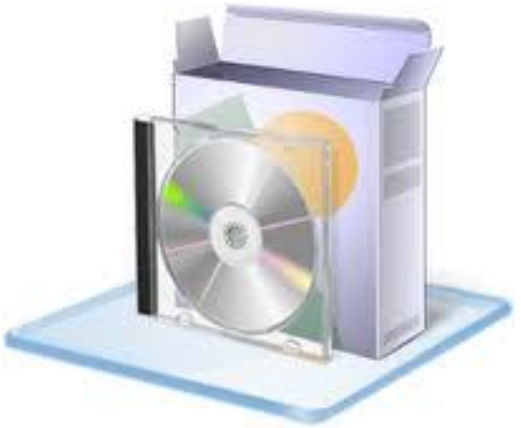
Software can be…



- a component, part or accessory of a medical device;
- itself a medical device;
- used in the production or development of a medical device;
- used in a manufacturer's Quality System (QS).

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WHAT MAKES SOMETHING A MEDICAL DEVICE?

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What makes an item a medical device?

- There are many definitions of a medical device around the world.
  - They are all very similar
  - They all have common attributes
- In some jurisdictions, there are kinds of medical devices, each with their own law or regulation
  - Active Implantable Medical Device
  - In Vitro Diagnostic Medical Device
  - (other) Medical Device
- The GHTF has created a consensus definition of a medical device
  - (Global Harmonization Task Force)
  - http://www.ghtf.org/

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The GHTF definition:

- any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, **intended by the MANUFACTURER** to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

  diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, treatment, alleviation of or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process,

  –supporting or sustaining life,

  –control of conception,

  –disinfection of medical devices,

  –providing information for medical purposes by means of in vitro examination of specimens derived from the human body,

  and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Key elements

- **Intended by the MANUFACTURER**

– The objective intent of the manufacturer as indicated in the labelling

– Labelling includes advertising and oral presentations by sales people as well IFU or Technical Data sheets.

Example: hammer

– The intent of the manufacturer (as labelled) can turn a general purpose device into a medical device

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Key elements:

- **for one or more of the specific purpose(s) of diagnosis or monitoring of disease or injury**
  - What is the labelled purpose of the item?
  - Is it intended to be used to diagnose or monitor patient(s) regarding disease or injury?
- Examples:
  - hose adaptor
  - HL7 protocol converter versus network switch
  - clinical information software
  - clinical decision support software
  - electronic health record software

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A quick summary:

- Software **intended by the MANUFACTURER** for one or more of the specific purpose(s) of diagnosis or monitoring of disease or injury
  - What is the labelled purpose of the software?
  - Is the software intended to be used to diagnose or monitor? patient(s) regarding disease or injury?
  - Is the software an accessory to a medical device?
    - Accessories can be treated as part of medical device, or
    - Accessories can be treated as medical devices in their own right
  - Is the software transforming existing information or creating new information about a patient?

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HEALTH CANADA

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Health Canada

- Canada explicitly recognizes that software can be a medical device
  http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/md_notice_software_im_avis_logicels-eng.php
- Canada has released and is enforcing their new guidance document
  - It clearly indicates that they consider it possible for software to be a medical device
  - It classifies these devices based on their classification rules
  - Class II Software required a license by 2011-09 and Class I software by 2011-02

Health Canada

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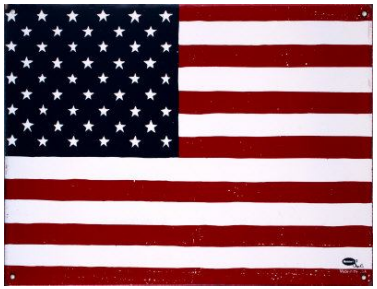
Health Canada

- Any patient management software used only for storing, acquiring, transferring or viewing data, or images is considered a **Class I** medical device
- Any patient management software with capabilities beyond basic data visualization, acquisition, transfer and storage is considered a **Class II** medical device

– includes any patient management software involved in data manipulation, data analysis, data editing, image generation, determination of measurements, graphing, flagging of results, identifying a region of interest or performing calculations (if the software performing calculations directly impacts diagnosis and/or treatment of a patient)

– Free and Open-Source Software (FOSS) that is used for patient management is subject to the same regulatory requirements



UNITED STATES (FDA)

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US FDA

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

- 'Standalone' software can be
  - not a medical device (not within the FDA's jurisdiction)
  - a device for which FDA exercises 'enforcement discretion'
  - classified as class I (general controls), i.e. typically no 510(k)
  - classified as class II (special controls in addition to general controls), i.e. typically 510(k)
  - classified as class III (premarket approval), i.e. PMA

Examples include: central stations, PACS, clinical information, electronic health record, decision support, various 'protocol converters' e.g. HL7 translators

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US FDA Guidances

- Software guidances
  - 0938 (2005) - General Principles of Software Validation; Final Guidance for Industry and FDA Staff
    - Replacement expected soon
    - FDA recently Recognized the IEC 62304 lifecycle process standard
  - 0585 (1999) - Off-The-Shelf Software Use in Medical Devices
    - Replacement expected soon
  - 1741 (2011) - draft Mobile Medical Applications
  - 0337 (2005) - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- product classifications that apply to software medical devices
  - LIS (lab information systems)
  - PACS (picture archiving systems)
  - MDDS (medical device data systems)

US FDA: MDDS

- The new MDDS final classification regulation:
  Class I, 510(k) exempt
  - Many such devices were previous Class III (needed PMA)
  - Not just limited to software, but most MDDS are software devices
  - Is a device that is intended to provide one or more of the following uses and function, **without controlling or altering the functions or parameters of any connected medical device**
  - An MDDS is **not intended** to be used in connection with **active patient monitoring**

SUMMARY

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Summary

- No special regulatory process for Software as a Medical Device
- A Medical Device is a Medical Device…
- Guidances are available
- Standalone software
  - can be a medical device in Canada & the US and can have any classification
- Software can be a 'component' of a medical device
- To be a medical device, software must
  - do something as intended by its manufacturer
  - be for the purpose of diagnosis or monitoring of disease or injury

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One last note…

To new developers of software that is a medical device:

Welcome to the wonderful world of
medical device regulation

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Thank you