A SYSTEM may include:
- any software
- any electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces and a communications protocol
- any combination of above

Is the SYSTEM intended (i.e., “labeled” or advertised) for connection to a medical device?

Does the SYSTEM itself control or alter functions or alter parameters of a medical device?

Is the SYSTEM used in connection with active monitoring systems (i.e., monitoring to facilitate immediate clinical actions ... e.g., remote alarms)?

SYSTEM is not a MDDS but is another category of Medical Device and likely subject to more regulation

SYSTEM is a MDDS

Has healthcare delivery organization (HDO) either
- put together hardware and/or software into system or
- added or otherwise modified SYSTEM hardware and/or software provided by original MDDS manufacturer?

HDO is not manufacturer of this MDDS and not required to meet FDA’s MDDS regulations for this MDDS

HDO is considered a manufacturer by FDA and must
- register as manufacturer with FDA
- list MDDS with FDA
- implement Adverse Event Reporting according to FDA’s Medical Device Reporting (MDR) requirements
- establish Good Manufacturing Practices (GMP) according to FDA’s Quality System (QS) requirements

©2012 HIMSS For more information visit www.himss.org
Contact Jonathan French, Dir, HIS at jfrench@himss.org

Disclaimer
This Flow Chart is presented for informational purposes only, and none of its content should be construed as legal advice. HIMSS members are strongly encouraged to read the respective legislative texts and/or consult with legal counsel. If you have any questions regarding this analysis, or HIMSS activities, please contact us. Visit our website for the latest developments.