JUL 0 8 2014

510(k) SUMMARY

K141102

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Hospira, Inc
Address	275 North Field Dr, Lake Forest, IL 60045
Phone number	858-391-1142
Fax number	224-212-5401
Establishment Registration Number	3005579246
Name of contact person	Tom Gutierrez
Date prepared	April 28, 2014
Name of device	
Trade or proprietary name	Hospira MedNet™ Medication Management Suite
Common or usual name	Infusion Pump Accessory Software
Classification name	Infusion Pump
Classification panel	General Hospital
Regulation	880.5725
Product Code(s)	FRN
Legally marketed device(s) to which equivalence is claimed	Hospira MedNet™ Medication Management Suite (MMS), cleared under K042609.
Reason for 510(k) submission	Software Changes
Device description	The Hospira MedNet™ Medication Management Suite (MMS) is an optional software product intended for use in healthcare facilities by trained healthcare professionals to facilitate networked communications (wired or wireless) between MMS compatible hospital information systems and compatible infusion pumps, The MMS provides healthcare professionals with the capability to send, receive, and store information from infusion pumps. The bi-directional communication includes infusion parameters, pump default configurations, pump location, history, events, trending, alarms and status. The MMS cannot remotely start, modify, or

	terminate ongoing infusions.
Intended use/ Indications for use of the device	The Hospira MedNet™ Medication Management Suite (MMS) is intended to facilitate networked communication between MMS compatible computer systems and Hospira Infusion pumps. The MMS provides trained healthcare professionals with the capability to send, receive, report, and store information from interfaced external systems, and to configure and edit infusion programming parameters. The MMS is intended to provide a way to automate the programming of infusion parameters, thereby decreasing the amount of manual steps necessary to enter infusion data. All data entry and validation of infusion parameters is performed by a trained healthcare professional according to physician's orders.

Summary of the technological characteristics of the device compared to the predicate device

Characteristic	Subject Device Hospira MedNet™ Medication Management Suite	Predicate Hospira MedNet™ Medication Management Suite K042609
Drug Library Editor (DLE)	Yes	Yes
DLE on PC		
Manage Download and Uploading via server	Yes	Yes
Configure Pumps	Yes	Yes
Manage Pump Logs	Yes	Yes
Multiple Drug entries per CCA	Yes	Yes
Multiple CCAs	Yes	Yes
Pre-populating pump	Yes	Yes
Wireless Communications	Yes	Yes
Bi-directional Communications	Yes	Yes

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE*

Non-Clinical Performance Test Summary

Verification and validation activities for Hospira MedNet™ software confirmed that the software meets user needs and design inputs.

Verification and validation testing was conducted and confirmed that the new feature design requirements were met. Additionally, pre-existing design requirements were re-tested. It was re-confirmed that Hospira MedNet™ continued to meet all pre-existing design requirements.

Risk management activities are incorporated in to the design and development process and a Safety Assurance Case has been generated to demonstrate the safety of the Hospira MedNet™ Medication Management Suite.

Human Factors studies have been conducted to validate the effectiveness of use related error mitigations.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical Performance Data/Information

No clinical trials have been performed. The modifications described in the submission do not meet the clinical testing criteria outlined in the FDA guidance "Total Product Life Cycle: infusion Pump –Premarket Notification {510(k)} Submissions (DRAFT GUIDANCE) issued in April 23, 2010, given:

- Hospira MedNet is not a new device
- there were no changed or modification in the intended use of the device
- the modifications were not intended to correct problems with the design of the user interface or usability of the product

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The results of the verification and validation testing as well as the risk analysis applied, supported by the Human Factors studies, demonstrate that the modifications described in the submission met design specifications and the device as a whole continues to be safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 8, 2014

Hospira, Incorporated
Mr. Tom Gutierrez
Associate Director
Global Regulatory Affairs
275 North Field Drive
Lake Forest, IL 60045

Re: K141102
Trade/Device Name: Hospira MedNet™ Medication Management Suite
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: June 6, 2014
Received: June 9, 2014

Dear Mr. Gutierrez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141102

Device Name

Hospira MedNet™ Medication Management Suite

Indications for Use *(Describe)*

The Hospira MedNet™ Medication Management Suite (MMS) is intended to facilitate networked communication between MMS compatible computer systems and Hospira Infusion pumps. The MMS provides trained healthcare professionals with the capability to send, receive, report, and store information from interfaced external systems, and to configure and edit infusion programming parameters.

The MMS is intended to provide a way to automate the programming of infusion parameters, thereby decreasing the amount of manual steps necessary to enter infusion data. All data entry and validation of infusion parameters is performed by a trained healthcare professional according to physician's orders.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by
Richard C. Chapman -S
Date: 2014.07.08
10:04:40 -04'00'

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