DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 16, 2015

Hospira, Incorporated
Yuliya Matlin, M.S., M.B.A.
Associate Director of Global Regulatory Affairs
275 North Field Drive
Lake Forest, Illinois 60045

Re: K141789
Trade/Device Name: Plum 360™ Infusion System with Hospira Mednet™, Smart Card Plug 'N Play CE 3.0 Upgrade Module for Plum A+™ Infusion System, and Plum Administration Sets
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, PHC, FPA
Dated: December 15, 2014
Received: December 17, 2014

Dear Ms. Malin:

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,

Tina Kiang -S

for Erin I. Keith, M.S.
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)*
K141789

Device Name
Plum 360 Infusion System with Hospira Mednet
Smart Card Plug 'N Play CE 3.0 Upgrade Module for Plum A+ Infusion System
Plum Administration Sets

Indications for Use *(Describe)*
Plum 360™ Infusion System with Hospira MedNet™ and Plum A+™ (360 Enabled™) Infusion System are indicated for use in parenteral, enteral and epidural therapies and the administration of whole blood and blood products.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary of Safety and Effectiveness

K141789

Submitter Information	
Name	Hospira, Inc.
Address	275 N Field Drive, Lake Forest, IL 60045 USA
Phone Number	224-212-4857
Fax Number	224-212-5402
Establishment Registration Number	3005579246
Name of Contact Person	Yuliya Matlin, M.S., M.BA
Date Prepared	June 30, 2014
Name of Device	
Trade or Proprietary Name	Plum 360™ Infusion System with Hospira MedNet™ Smart Card Plug'n' Play Module with CE 3.0 for Plum A+™ Infusion System Plum™ Administration Sets
Common or Usual Name	Infusion Pumps, Infusion safety management software & Intravascular Administration Sets
Classification Name	Infusion Pumps, Infusion safety management software & Intravascular Administration Sets
Classification Panel	80
Regulation(s)	21 CFR 880.5725 & 21 CFR 880.5440
Product Code(s)	FRN, PHC, FPA
Legally Marketed Device(s) To Which Equivalence is Claimed	Infusion System: Plum A+™ Infusion System with Hospira Mednet™ (K042081) Administration Sets: Abbott Plum A+ Pump and Sets (K982159) Lifeshield Latex-Free Microbore Extentsion Set, Model 14949 and Others (K052722) Hospira Enteral Feeding Set, Model 20640 (K061432) Hospira Infusion Blood Sets (K101677) Hospira Plum Infusion Set; Hospira Infusion Set with Yellow Stripe Tubing (K103224)

	Infusion Sets (K103344) Lifeshield Vision Infusion Set with Pre-pierced Reseal (K113683)
Reason for 510(k) Submission	Introduction of the next generation of Plum™ Infusion System-Plum 360™ Infusion System with Hospira MedNet™ with enhanced software, hardware and connectivity features. Introduction of an optional Smart Card Plug 'n' Play module with CE 3.0 for Plum A+™ Infusion System upgrade. Changes to secure lock component of Plum™ Administration Sets.
Device Description	The Plum 360™ Infusion System with Hospira MedNet™ remains a volumentric Infusion System intended for use in parenteral, enteral and epidural therapies and the administration of whole blood and blood products. Dedicated administration sets are used for delivery of infusion therapy to the patient. The device has a user interface consisting of LCD display, front panel numeric keypads and keys, audible and visual indicators, audible indicator volume control, nurse call interface, network interface connectors, the drug library, and software that provides pre-defined display screens for therapy programming. The continued use of the Hospira MedNet™ Software allows communication between the Infusion Pump, Hospira MedNet™ server and the facility's communication systems.
Intended Use/Indication For Use	Plum 360™ Infusion System with Hospira Mednet™ and Plum A+™ (360 Enabled™) Infusion System are indicated for use in parenteral, enteral and epidural therapies and the administration of whole blood and blood products.
Summary of the Technological Characteristics of the Device Compared to the Predicate Device	
Plum 360™ Infusion System with Hospira MedNet™ employs the same fundamental scientific technology, principles of operation and intended/indications for use. In addition, the subject device includes the following notable characteristics: • Latest CPU software version 15.0 featuring drug library enhancements, autoprogramming and alarm management enhancments. • Enhanced connectivity engine CE 3.0 with imporved Wi-Fi Performance, network connectivity and throughput to Hospira MedNet™ • Enhanced hardware including egronomic enclosure, proximal tubing guides, ratcheting pole clamp and keypad. • Enhancements to dedicated administration sets to include a modified secure lock. • An optional Smart Card Plug 'n' Play with CE 3.0 Module allows Plum A+™ Infusion System upgrades to the latest CPU software version 15.0 and CE 3.0, resulting in Plum A+™ (360 Enabled™) Infusion System configuration.	
Performance Data	
Summary of Non-Clinical Tests Conducted For Determination of Substantial Equivalence	
Performance Test Summary - Subject Device System verification and validation activities for subject devices confirmed that the system meets user needs and design inputs. All the testing met the acceptance criteria. Risk management activities are incorporated in to the design and development process and safety assurance cases has been generated to demonstrate the safety of the subject devcies. Risk management as well as verification and validation activities incorporate the principles of applicable FDA guidance such as *"Total Product Life Cycle: infusion Pump –Premarket Notification [510(k)] Submissions (DRAFT GUIDANCE)"*	

issued in April 23, 2010 and "*General Principles of Software Validation; Final Guidance for Industry and FDA Staff*," issued January 11, 2002.

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

Characteristics	Standard/Test/FDA Guidance	Results Summary
Electrical and Mechanical Safety	ANSI/AAMI ES60601-1 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance, 2005 / (R)2012 / C1:2009 / (R)2012, including Amendment 1:2012	PASS
Electromagnetic Compatibility	IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, Edition 3:2007-03	PASS
Alarms System	IEC 60601-1-8 Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems, Edition 2.0 2006-10	PASS
Infusion Pump Basic Safety and Essential Performance	IEC 60601-2-24 Medical Electrical Equipment – Part-24: Particular Requirements for the Basic Safety and Essential Performance of Infusion Pump and Controllers, Edition 2.0 2012-10	PASS
Biocompatibility	ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, Fourth edition 2009-10-15	PASS

Summary of Clinical Tests Conducted for Determination of Substantial Equivalence and/or of Clinical Information

Clinical evaluation is not required for this submission to support substantial equivalence. Human factors studies have been conducted on subject devcies demonstrating passing results.

Conclusion

Hospira, Inc. considers Plum 360™ Infusion System Hospira MedNet™ and Plum A+™ (360 Enabled™) Infusion System with Hospira MedNet™ to be as safe and effective as its predicate devices. Therefore, Plum 360™ Infusion System compatible with Hospira MedNet™ and Plum A+™ (360 Enabled™) Infusion System with Hospira MedNet™ are substantially equivalent to predicate devices.