DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 28, 2017

Hospira, Inc
Keith Dunn
Associate Director, Global Regulatory Affairs, Devices
275 North Field Drive
Lake Forest, Illinois 60045

Re: K161469
Trade/Device Name: Plum 360™ Infusion System with MedNet/ Smart Card Plug 'n' Play Module
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, PHC, FPA
Dated: February 22, 2017
Received: February 28, 2017

Dear Keith Dunn:

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" (21 CFR 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, Ph.D.
Acting 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)*
K161469

Device Name
Plum 360™ Infusion System with Hospira MedNet™/ Smart Card Plug 'n' Play Module

Indications for Use *(Describe)*
Plum 360™ Infusion System with Hospira MedNet™ is 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Section 5: 510(k) Summary

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

Submitter Information	
Name	ICU Medical
Address	D-393 600 North Field Drive Lake Forest, IL. 60045
Phone number	224-212-4898
Fax number	224-212-5402
Establishment Registration Number	3005579246
Name of contact person	Yuliya Matlin
Date prepared	March 28, 2017
Name of device	
Trade or proprietary name	Plum 360™ Infusion System with MedNet/ Smart Card Plug 'n' Play Module
Common or usual name	Infusion Pump
Classification name	Infusion Pump
Classification panel	80
Regulation	21 CFR 880.5725
Product Code(s)	FRN, PHC, FPA
Legally marketed device(s) to which equivalence is claimed	Infusion System: Plum 360™ Infusion System with MedNet / Smart Card Plug 'n' Play (K141789)
Device description	The Plum 360™ Infusion System withMedNet / Smart Card Plug 'n' Play Module remains a volumetric 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 alphanumeric 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 MedNet Software allows communication between the Infusion Pump, MedNet server and the facility's communication systems.
Indication for Use	The Plum 360™ Infusion System with Hospira MedNet ™ is indicated for use in parenteral, enteral, and epidural therapies and the administration of whole blood and blood products.

<table>
<tr><td>Summary of Indications for Use Compared to Predicate Device</td><td>With exception to the system name, the Indications for Use is identical to the predicate device.</td></tr>
<tr><td>Summary of the Technological Characteristics Compared to Predicate Device</td><td>Plum 360™ Infusion System with MedNet/ Smart Card Plug 'n' Play employs the same fundamental scientific technology, and principles of operation and intended use as the predicate device. In addition, Plum 360™ Infusion System with MedNet/ Smart Card Plug 'n' Play Module has the following technological characteristic enhancements compared to predicate device with the following changes related to the bolus feature:
<table>
<tr><th>Feature</th><th>Subject Plum 360 Infusion System with Bolus Feature Compared to Predicate Plum 360 Infusion System</th></tr>
<tr><td>CPU Software</td><td>Updated to 15.10
Software differences included introduction of bolus functionality and associated user interface modifications, addition of the dosing units and modifications to programmable dose ranges, infusion log updates and cybersecurity enhancements</td></tr>
<tr><td>Communication Engine (CE)</td><td>Updated to 3.03
Software differences included Cybersecurity enhancements and changes to support additional bolus functionality</td></tr>
</table></td></tr>
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Performance Data – Non Clinical Testing

The following standards and associated methods were applied to demonstrate the Plum 360™ Infusion System with MedNet / Smart Card Plug 'n' Play Module is substantially equivalent to the current device after the historical and subject changes are applied

- IEC 60601-1Medical Electrical Equipment-Part 1: General Requirement for Basic Safety and Essential Performance, 2005/(R)2012/C1:2009/(R)2012, Including Amendment 1:2012
- IEC 60601-2-24 Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers, Edition 2.0 2012
- 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
- IEC 60601-1-8 Collateral Standard: General Requirements, test and guidance for alarm systems in medical electrical equipment and medical electrical systems, Edition 2.0 2006

A risk analysis was applied to assess the impact of modifications necessary to include a bolus feature with the system. The analysis demonstrates the changes do not introduce new risks to the patient. All risks which are identified have been mitigated as low as reasobaly possible.

The device safety assurance case was updated to include the bolus feature that is being added to the Plum 360™ Infusion System with MedNet / Smart Card Plug 'n' Play Module, as recommended in the FDA guidance document, Infusion Pumps Total Product Life Cycle

The assurance case defined the device system, including the indications for use, system specifications, use environments, and user population. The supporting assurance arguments covered the following attributes:

- All potential risks have been mitigated and residual risk is acceptable.
- Design verification and validation of device specifications are adequate.
- Device reliability is adequate.

The following evidence was included in the assurance case:

- Performance Test Summary: System verification and validation activities for Plum 360 Infusion System confirmed that the system meets user needs and design inputs. All the testing met the acceptance criteria.
- Human factors evaluations have been conducted to validate the effectiveness of the bolus feature.
- Software verification and validation as recommended in the following FDA guidance documents:
  - Infusion Pumps Total Product Life Cycle
  - Content of Premarket Submissions for Software Contained in Medical Devices
  - Applying Human Factors and Usability Engineering to Medical Devices

Electrical and Electromagnetic Compatibility testing were conducted. Updates due to the bolus feature complies with following standard:

Infusion Pump Basic Safety and Essential Performance	IEC 60601-2-24 Medical Electrical Equipment – Part-24: Edition 2.0 2012-10

Performance Data – Clinical Testing	Clinical evaluation is not required for this submission to support substantial equivalence. Human Factors studies have been conducted on subject devices, demonstrating passing results.

CONCLUSIONS DRAWN FROM NON-CLINICAL DATA

The conclusions drawn from the non-clinical tests demonstrate that the Plum 360™ Infusion System with MedNet / Smart Card Plug 'n' Play Module is substantially equivalent to the predicate device.