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

January 6, 2017

Hospira, Inc.
Charles Neitzel
Senior Regulatory Affairs Specialist
375 Field Drive
Lake Forest, Illinois 60045

Re: K161036
Trade/Device Name: Hospira Extension Set and Hospira Primary Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA, ODA
Dated: December 2, 2016
Received: December 5, 2016

Dear Charles Neitzel:

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)*
K161036

Device Name
Hospira Extension Set
Hospira Primary Set

Indications for Use *(Describe)*
Hospira Extension sets are indicated for the delivery of fluids from a container to a patient's vascular system.

Hospira Primary sets are indicated for the delivery of fluids from a container to a patient's vascular system.

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.

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

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510(k) Summary – K161036

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

Submitter Information	
Name	Hospira, Incorporated
Address	D-393, Bldg. H3 375 North Field Drive Lake Forest, IL. 60046
Phone number	(224) 212-6087
Mobile number	N/A
Fax number	(224) 212-5401
Establishment Registration Number	3005579246 (Owner/Operator #9063339)
Name of contact person	Charles Neitzel, Senior Regulatory Affairs Specialist
Date prepared	12 April 2016
Name of device	
Trade or proprietary name	Hospira Extension Set Hospira Primary Set
Common or usual name	I.V. Administration Sets
Classification name	Intravascular Administration Set, 21 CFR 880.5440, Class II
Product Code(s)	FPA OJA
Legally marketed device(s) to which equivalence is claimed	Hospira Extension Sets – K142974 Hospira Primary Sets – K143015
Reason for 510(k) submission	The change addressed in this submission is: 1. Hospira is replacing the current Dial-A-Flo flow control device with a new Dial-A-Flo flow control device.
Device description	The Hospira Extension Sets and the Hospira Primary Sets are intended for use as gravity sets. Hospira Extension sets are comprised of various components including the following: male luer adapter with cap, tubing, female luer adapter, , in-line adapter, injection site assembly, and Dial-A-Flo. Hospira Primary Sets are comprised of a variety of components, at a minimum including a male luer adapter with a spin collar, a piercing pin assembly, a cap on each adapter, injection site assembly, Dial-A-Flo assembly and tubing. Extension sets and Primary Sets are configured to ensure the intended use of the device is met. The sets are disposable devices for single patient use.
Intended Use of Device	Hospira Extension sets are indicated for the delivery of fluids from a container to a patient's vascular system. Hospira Primary sets are indicated for the delivery of fluids from a container to a patient's vascular system.

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Predicates** **K142974 & K143015**		**Proposed Device**
Indications for Use	Hospira Extension Sets and Hospira Primary Sets are indicated for the delivery of fluids from a container to a patient's vascular system.		Hospira Extension Sets and Hospira Primary Sets are indicated for the delivery of fluids from a container to a patient's vascular system.
Design and Materials of Construction	The design and materials of construction are as cleared under the predicate 510(k)		The design and materials of construction remain the same as the predicate product with the following exception: • Hospira is changing the flow control device currently used in Extension Sets and Primary Sets.
	Proposed Changes to Flow Control Device		
	[redacted]	Predicate	Proposed
	Component	Dial-A-Flo	Dial-A-Flo
	Manufacturer	ICU Medical, Utah	GVS, Italy
	Assembly Materials	Acrylic receiving member Ethylene Propylene Gasket Acrylic metering plate Delivery member	ABS Plastic SEBS thermoplasctic elastomer
	Regulatory Length	1.7 in	34.3 mm
	Regulator Diameter	0.850 in	29.8 mm
	Delivery Member Length	0.510 in	9 mm
	Delivery Member Diameter	0.200 in	3.5 mm
	Tubing Inner Diameter (I.D.) and Outer Diameter (O.D.)	0.100" I.D. x 0.138" O.D.	Same
	Set Length	Available in 18", 79", and 89".	Same

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

<table>
<tr><th>Characteristic</th><th>Predicates
K142974 & K143015</th><th>Proposed Device</th></tr>
<tr><td>Summary of non-clinical tests for determination of substantial equivalence</td><td>All materials of construction for Hospira I.V. Administration sets meet the applicable material test requirements for ISO 10993</td><td>New data has been generated demonstrating that all materials of construction for Hospira I.V. Administration Sets meet the applicable material test requirements for ISO 10993.
<table>
<tr><th>ISO Standard</th><th>Biological Effect Tested</th></tr>
<tr><td>ISO 10993-4</td><td>Hemocompatibility</td></tr>
<tr><td>ISO 10993-5</td><td>Cytotoxicity</td></tr>
<tr><td>ISO 10993-10</td><td>Sensitization</td></tr>
<tr><td rowspan="5">ISO 10993-11</td><td>Intracutaneous Irritation</td></tr>
<tr><td>Systemic Toxicity</td></tr>
<tr><td>Subacute Toxicity</td></tr>
<tr><td>Subchronic Toxicity</td></tr>
<tr><td>Pyrogenicity</td></tr>
</table></td></tr>
<tr><td>Summary of Performance Testing</td><td>Performance testing was conducted to ensure the device performs as intended in accordance with applicable standards. All testing is acceptable.

The product Sterility Assurance Level is 10^{-6}.</td><td>New performance data has been generated to ensure the device performs as intended in accordance with ISO 8536-4. All testing is acceptable. ISO 594-1 and ISO 594-2 compliance is covered with the predicate 510(k)s K142974 and K143015.
<table>
<tr><th>ISO Standard</th><th>Section Tested</th></tr>
<tr><td rowspan="10">ISO 8536-4</td><td>6.1 Particulate Contamination</td></tr>
<tr><td>6.2 Leakage</td></tr>
<tr><td>6.3 Tensile Strength</td></tr>
<tr><td>6.6 Tubing</td></tr>
<tr><td>6.7 Fluid Filter</td></tr>
<tr><td>6.9 Flow Regulator</td></tr>
<tr><td>6.10 Flow Rate</td></tr>
<tr><td>6.11 Injection Site</td></tr>
<tr><td>6.12 Male Conical Fitting</td></tr>
<tr><td>6.13 Protective Caps</td></tr>
</table>
The product Sterility Assurance Level is 10^{-6}.</td></tr>
</table>

Conclusion

Hospira Extension Sets and Hospira Primary Sets meet the functional claims and intended use as described in the product labeling. The Hospira Extension Sets and Hospira Primary Sets are substantially equivalent to the Hospira Extension Sets and Hospira Primary Sets cleared under K142974 and K143015, respectively.