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

March 4, 2015

Hospira, Inc.
Charles Neitzel
Senior Regulatory Affairs Associate
D-0393 Bldg. H3
375 North Field Street
Lake Forest, IL 60045

Re: K143087
Trade/Device Name: Hospira Blood Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: January 29, 2015
Received: January 30, 2015

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" (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,

Erin I. Keith -S

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K143087

Device Name
Hospira Blood Sets

Indications for Use *(Describe)*
Hospira Blood sets are indicated for the delivery of fluids including but not limited to blood and blood products 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)

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Section 5 510(k) Summary

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

Submitter Information	
Name	Hospira, Incorporated
Address	D-393, Bldg. H3 375 North Field Drive Lake Forest, IL. 60046
Phone number	(224) 212-6087
Fax number	(224) 212-5401
Establishment Registration Number	3005579246 (Owner/Operator #9063339)
Name of contact person	Charles Neitzel, Senior Regulatory Affairs Specialist
Date prepared	10/24/2014
Name of device	
Trade or proprietary name	Blood Sets
Common or usual name	I.V Administration Sets
Classification name	Intravascular Administration Set, 21 CFR 880.5440, Class II
Product Code(s)	FPA
Legally marketed device(s) to which equivalence is claimed	Hospira Infusion Blood Sets – K101677
Reason for 510(k) submission	The changes addressed in this submission include: • Modification to Secure Lock Male Luer
Device description	The Hospira Blood Sets with Secure Lock are intended for use as gravity sets. Hospira Blood sets are comprised of various components including the following: male luer adapter with cap, tubing, flow control device, piercing pin assembly, burette assembly / blood pump assembly / or blood cylinder assembly, and injection site assembly. Blood sets are configured to ensure the intended use of the device is met. Hospira Blood sets are intended for the delivery of fluids from a container to a patient's vascular system. The sets are disposable devices for single patient use.
Intended Use of Device	Hospira Blood sets are indicated for the delivery of fluids including but not limited to blood and blood products from a container to a patient's vascular system.

<table>
<tr><th colspan="3">Summary of the technological characteristics of the device compared to the predicate device</th></tr>
<tr><th>Characteristic</th><th>Predicate</th><th>Proposed Device</th></tr>
<tr><td>Indications for Use</td><td>LifeShield Infusion Sets are intended for the delivery of fluids including but not limited to blood and blood products from a container to a patient’s vascular system.</td><td>Hospira Blood sets are indicated for the delivery of fluids including but not limited to blood and blood products from a container to a patient’s vascular system.</td></tr>
<tr><td>Design and Materials of Contruction</td><td>The design and materials of construction are as cleared under the predicte 510(k)

Hospira Blood Sets are comprised of the following minimum components:

<table>
<tr><td>Component</td><td>Material Type</td></tr>
<tr><td>Male Luer Adapter
- Male / Luer Adapter
- Spin Collar</td><td>
- Acrylic
- Polycarbonate</td></tr>
<tr><td>Hood / Cap</td><td>Polypropylene</td></tr>
<tr><td>Tubing</td><td>PVC, Non-Pthalatae</td></tr>
<tr><td>Flow Control Device</td><td>High Density Polyethylene or ABS</td></tr>
<tr><td>Piercing Pin Assembly</td><td>ABS / Polyetylene / Acrylic / Nylon</td></tr>
</table>
</td><td>The design and materials of construction remain the same as the predicate product with the following exceptions:
1. The male luer adapter material is changing to an alternate acrylic material.
Minor dimensional modifications are being made to the male luer adapter to enhance connection with female luers.</td></tr>
</table>

<table>
<tr>
<td>Summary of non-clinical tests for determination of substantial equivalence</td>
<td>All materials of construction for Hospira Blood Sets meet the applicable material test requirements for ISO 10993.
<table>
<tr><td>Cytotoxicity</td><td>ISO 10993-5</td></tr>
<tr><td>Sensitization</td><td>ISO 10993-10</td></tr>
<tr><td>Intracutaneous Reactivity</td><td>ISO 10993-10</td></tr>
<tr><td>Systemic Toxicity</td><td>ISO 10993-11</td></tr>
<tr><td>Subacute Toxicity</td><td>ISO 10993-11</td></tr>
<tr><td>Subchronic Toxicity</td><td>ISO 10993-11</td></tr>
<tr><td>Pyrogenicity</td><td>ISO 10993-11</td></tr>
<tr><td>Hemocompatibility</td><td>ISO 10993-4</td></tr>
</table>
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<td>New data has been generated demonstrating that all materials of construction for Hospira Blood Sets meet the applicable material test requirements for ISO 10993.
<table>
<tr><td>Cytotoxicity</td><td>ISO 10993-5</td></tr>
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</td>
</tr>
</table>

<table>
<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}.
<u>ISO 1135-4:2012</u>
<table>
<tr><td>Particulate Contamination</td></tr>
<tr><td>Leakage</td></tr>
<tr><td>Tensile Strength</td></tr>
<tr><td>Closure-piercing pin</td></tr>
<tr><td>Tubing</td></tr>
<tr><td>Blood Filter</td></tr>
<tr><td>Drip chamber and drip tube</td></tr>
<tr><td>Flow Regulator</td></tr>
<tr><td>Flow Rate</td></tr>
<tr><td>Injection Site</td></tr>
<tr><td>Male Conical Fitting</td></tr>
<tr><td>Protective Caps</td></tr>
</table>
<u>ISO 594 Part 1: 1986</u>
<table>
<tr><td>Gauging</td></tr>
<tr><td>Liquid Leakage</td></tr>
<tr><td>Air Leakage</td></tr>
<tr><td>Separation Force</td></tr>
<tr><td>Stress Cracking</td></tr>
</table>
<u>ISO 594 Part 2: 1998</u>
<table>
<tr><td>Gauging</td></tr>
<tr><td>Leakage (liquid)</td></tr>
<tr><td>Leakage (air)</td></tr>
<tr><td>Separation Force</td></tr>
<tr><td>Unscrewing Torque</td></tr>
<tr><td>Ease of Assembly</td></tr>
<tr><td>Resistance to Overriding</td></tr>
<tr><td>Stress Cracking</td></tr>
</table>
</td>
<td>New performance data has been generated to ensure the device performs as intended in accordance with ISO 594-1, ISO 594-2, ISO 1135-4. All testing is acceptable.

The product Sterility Assurance Level is 10^{-6}
<u>ISO 1135-4:2012</u>
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<tr><td>Particulate Contamination</td></tr>
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Conclusion

Hospira Blood Sets meet the functional claims and intended use as described in the product labeling. The safety and effectiveness are substantially equivalent to the Infusion Blood Sets cleared under K101677.