



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

January 19, 2016

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

Re: K151969

Trade/Device Name: Hospira Extension Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Sets
Regulatory Class: II
Product Code: FPA
Dated: December 15, 2015
Received: December 17, 2015

Dear Mr. 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,

 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

Indications for Use

510(k) Number (if known)

K151969

Device Name

Hospira Extension Sets

Indications for Use (Describe)

Hospira Extension 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.

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Section 5 510(k) Summary

A summary of 510(k) substantial equivalence information in accordance with the requirements of 21 CFR 807.92 for Hospira Extension 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	January 13, 2016
Name of device	
Trade or proprietary name	Hospira Extension 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	Extension Sets – K142974 Hospira Extension Sets – K142433
Reason for 510(k) submission	The changes addressed in this submission include: <ol style="list-style-type: none"> Hospira is changing the tubing material formulation currently used in Hospira Extension Sets. Hospira is replacing the needleless valve Clave™ component on certain IV administration Hospira Extension Sets with the MicroClave™ component.
Device description	The Hospira Extension 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, flow control device, in-line adapter, injection site assembly, and Dial-A-Flo. Extension sets are configured to ensure the intended use of the device is met. Hospira Extension 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 Extension set is intended 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	Predicate	Proposed Device															
Indications for Use	Hospira Extension Sets are indicated for the delivery of fluids from a container to a patient's vascular system.	Hospira Extension 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)	<p>The design and materials of construction remain the same as the predicate product with the following exceptions:</p> <ol style="list-style-type: none"> Hospira is changing the tubing material formulation currently used in Extension Sets. Hospira is replacing the Clave™ component on certain IV administration Extension Sets with the MicroClave™ component. <p>The MicroClave performs functionally the same as the Clave, for the same intended use, and is comprised of similar materials. The Microclave is a cleared component under ICU Medical 510(k) K970855 establishing substantial equivalence.</p>															
Summary of non-clinical tests for determination of substantial equivalence	All materials of construction for Hospira Extension Sets meet the applicable material test requirements for ISO 10993	<p>New data has been generated demonstrating that all materials of construction for Hospira Extension Sets meet the applicable material test requirements for ISO 10993.</p> <table border="1"> <thead> <tr> <th>ISO Standard</th> <th>Biological Effect Tested</th> </tr> </thead> <tbody> <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="4">ISO 10993-11</td> <td>Intracutaneous Reactivity</td> </tr> <tr> <td>Systemic Toxicity</td> </tr> <tr> <td>Suacute Toxicity</td> </tr> <tr> <td>Subchronic Toxicity</td> </tr> <tr> <td></td> <td>Pyrogenicity</td> </tr> </tbody> </table>	ISO Standard	Biological Effect Tested	ISO 10993-4	Hemocompatibility	ISO 10993-5	Cytotoxicity	ISO 10993-10	Sensitization	ISO 10993-11	Intracutaneous Reactivity	Systemic Toxicity	Suacute Toxicity	Subchronic Toxicity		Pyrogenicity
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<p>Summary of Performance Testing</p>	<p>Performance testing was conducted to ensure the device performs as intended in accordance with applicable standards. All testing is acceptable.</p> <p>The product Sterility Assurance Level is 10^{-6}.</p>	<p>New performance data has been generated to ensure the device performs as intended in accordance with ISO 594-1, ISO 594-2, and ISO 8536-4. All testing is acceptable.</p> <table border="1" data-bbox="1036 384 1515 1388"> <thead> <tr> <th>ISO Standard</th> <th>Section Tested</th> </tr> </thead> <tbody> <tr> <td rowspan="5">ISO 594-1</td> <td>4.1 Gauging</td> </tr> <tr> <td>4.2 Liquid Leakage</td> </tr> <tr> <td>4.3 Air Leakage</td> </tr> <tr> <td>4.4 Separation Force</td> </tr> <tr> <td>4.5 Stress Cracking</td> </tr> <tr> <td rowspan="7">ISO 594-2</td> <td>4.1 Gauging</td> </tr> <tr> <td>4.2 Liquid Leakage</td> </tr> <tr> <td>4.3 Separation Force</td> </tr> <tr> <td>4.4 Unscrewing Torque</td> </tr> <tr> <td>4.5 Ease of Assembly</td> </tr> <tr> <td>4.6 Resistance to Overriding</td> </tr> <tr> <td>4.7 Stress Cracking</td> </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> </tbody> </table> <p>Sterilization validation has been conducted based on the ANSI/AAMI/ISO 11137-1 and ANSI/AAMI/ISO 11737-1 international standards for sterilization of medical devices. All testing is acceptable. The product Sterility Assurance Level is 10^{-6}.</p>	ISO Standard	Section Tested	ISO 594-1	4.1 Gauging	4.2 Liquid Leakage	4.3 Air Leakage	4.4 Separation Force	4.5 Stress Cracking	ISO 594-2	4.1 Gauging	4.2 Liquid Leakage	4.3 Separation Force	4.4 Unscrewing Torque	4.5 Ease of Assembly	4.6 Resistance to Overriding	4.7 Stress Cracking	ISO 8536-4	6.1 Particulate Contamination	6.2 Leakage	6.3 Tensile Strength	6.6 Tubing	6.7 Fluid Filter	6.9 Flow Regulator	6.10 Flow Rate	6.11 Injection Site	6.12 Male Conical Fitting	6.13 Protective Caps
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Conclusion

Hospira Extension Sets meet the functional claims and intended use as described in the product labeling. Hospira Extension Sets are substantially equivalent to the predicate device.