DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 9.2015

Hospira, Incorporated
Mr. David Blonski
Director Regulatory Affairs
375 N. Field Drive
Lake Forest, IL 60046

Re: K142974
Trade/Device Name: Hospira Extension Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 10, 2014
Received: October 14, 2014

Dear Mr. Blonski:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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, 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 Statement

510(k) Number: K142974

Device Name: Hospira Extension Set

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

Prescription Use __X__ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5 510(k) Summary K142974

A summary of 510(k) safety and effectiveness 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) 212-5010
Mobile number	(224) 515-6807
Fax number	(224) 212-5401
Establishment Registration Number	3005579246 (Owner/Operator #9063339)
Name of contact person	David Blonski, Director Regulatory Affairs
Date prepared	Oct. 10, 2014
Name of device	
Trade or proprietary name	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	LifeShield Vision Infusion Sets – K113683 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 Extension Sets with Secure Lock 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, stopcock and Dial-A-Flo. Extension sets are configured to ensure the intended use of the device is met. Hospira Externsion 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 Set is intended for the delivery of fluids from a container to a patient's vascular system.	Hospira Extension Set is indicated for the delivery of fluids from a container to a patient's vascular system.
Design and Materials of Construction	The materials of construction for the proposed device are exactly the same as the materials for the predicate product	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. 2. Minor dimensional modifications are being made to the male luer adapter to enhance connection with female luers.
Summary of non-clinical tests for determination of substantial equivalence	All materials of constrction for Hospira Extension Sets meet the applicable material test requirements for ISO 10993	New data has been generated demonstrating that all materials of construction for Hospira Extension Sets meet the applicable material test requirements for ISO 10993.
Summary of Performance Testing	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}.	New performance data has been generated to ensure the device performs as intended in accordance with ISO 594-1, ISO 594-2, ISO 8536-4 and ISO 8536-10. All testing is acceptable. The product Sterility Assurance Level is 10^{-6}.

Conclusion

Hospira Extension Sets meet the functional claims and intended use as described in the product labeling. The safety and effectiveness are substantially equivalent to the LifeShield Vision Infusion Sets cleared under K113683 and Hospira Infusion Blood Sets cleared under K101677.