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

December 6, 2016

Hospira, Inc.
David Blonski
Director Regulatory Affairs
375 North Field Drive
Lake Forest, Illinois 60045

Re: K160492
Trade/Device Name: Hospira Sapphire Sets
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ
Dated: December 1, 2016
Received: December 2, 2016

Dear David 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 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 -S

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)*
K160492

Device Name
Hospira Sapphire Set

Indications for Use *(Describe)*
Hospira Sapphire 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.

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Section 5 510(k) Summary: K160492

A summary of 510(k) substantial equivalence information in accordance with the requirements of 21 CFR 807.92 for Hospira Sapphire Sets.

Submitter Information	
Name	Hospira, Incorporated
Address	D-393, Bldg. H3 375 North Field Drive Lake Forest, IL. 60046
Phone number	24-212-5010
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	2/19/2016
Name of device	
Trade or proprietary name	Hospira Sapphire Sets
Common or usual name	Infusion pump accessory
Classification name	Infusion Pump, 21 CFR 880.5725, Class II
Product Code(s)	MRZ
Legally marketed device(s) to which equivalence is claimed	Q Core Medical Sapphire Sets – K123049 (Predicate 510(k)) Hospira Plum Sets – K141789 (reference 510(k) for technological characteristics) Life Care PCA Infusion System – K043256 (reference 510(k) for technological characteristics)
Reason for 510(k) submission	New IV administration sets to be used with Q Core Medical Ltd.'s Sapphire Infusion System.
Device description	Hospira Sapphire Sets are intended for use with the Sapphire Infusion System. Hospira Sapphire sets are comprised of various components including the following: male luer adapter with cap, female luer with cap, piercing pin connector, sapphire cassette, tubing, flow control device, in-line adapter, injection site assembly, check valve, and burette chamber. Hospira Sapphire 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 Sapphire sets are intended for use with the Sapphire Infusion System to deliver fluids from a container to a patient's vascular system. Hospira Sapphire Sets are indicated for the delivery of fluids from a container to a patient's vascular system.
Indication for use	Hospira Sapphire 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	**Predicate**	**Proposed Device**
Indications for Use	The Q Core Sapphire infusion pump is intended for the controlled delivery through intravascular, subcutaneous, intra-arterial and epidural routes. The pump is designed to deliver saline, Total Parenteral Nutrition, lipids, IV medication, epidural medication, blood and blood products. The Sapphire pump includes the following infusion modes for all intended uses: Continuous, Intermittent, TPN, PCA, Multi-step, and Epidural. The pump is intended to be used by both licensed health care professionals in a clinical environment, and home users in an ambulatory environment. The Sapphire pump is designed to follow the patient through the various care areas, and in pre-hospital medical ground transportation. The dedicated Q Core administration sets for the Sapphire pump are intended for single-patient use and single-use only.	Hospira Sapphire Sets are indicated for the delivery of fluids from a container to a patient's vascular system.
Discussion of change in indication for use	The differences between the predicate and proposed indications for use stated above are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the proposed device. The predicate indication for use stated above is primarily related to use of the Sapphire Infusion pump with an inclusionary statement that the Q Core administration sets for the Sapphire pump are intended for single-patient use and single-use only. The Hospira Sapphire sets are intended for use with the Sapphire pump and as such are a component of the predicate device system. The proposed sets are also intended for single patient use and single-use only. The proposed Hospira Sapphire sets have the same intended use, and as indicated below are tested to the same performance standards as the predicate sets and therefore do not affect the safety and effectiveness predicate device system.	
Design and Materials of Construction	The design and materials of construction of all components for the set, with the exception of the Sapphire Cassette, are as cleared under the 510(k)s K141789 and K043256 which are reference 510(k)s for technological characteristics. The design and materials of construction of the Sapphire Cassette are as cleared under the predicate Q Core Medical Ltd. 510(k) K123049.	The design and materials of construction for all components of the sets remain the same as the predicate product.

Summary of non-clinical tests for determination of substantial equivalence	All materials of construction for Hospira Sapphire Sets meet the applicable material test requirements for ISO 10993 as demonstrated in the predicate 510(k)s.	All materials of construction for Hospira Sapphire Sets remain the same as the predicate product. Additional data has been generated demonstrating that Hospira Sapphire sets, which are comprised of a combination of Hospira IV set components with the Sapphire Cassette, meet the applicable material test requirements for ISO 10993 as follows: **ISO Standard** — **Biological Effect** 10993-4 — Hemocompatibility 10993-5 — Cytotoxicity 10993-10 — Sensitization Intracutaneous Irritation 10993-11 — Systemic Toxicity Subacute Toxicity Pyrogenicity
	Performance testing for all Hospira Sapphire set components, with the exception of the Sapphire Cassette, was conducted as indicated in the predicate 510(k)s to ensure the device performs as intended in accordance with applicable standards. All testing is acceptable. Performance testing for the Q Core Medical Ltd. Sapphire Cassette , was conducted as indicated in the predicate 510(k) to ensure the cassette performs with the Sapphire Pump 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 Hospira Sapphire Sets, a combination of Hospira IV set components with the Sapphire Cassette, perform as intended in accordance with: ISO 8536-4, 6.1 Particulate Contamination ISO 8536-4, 6.2 Leakage ISO 8536-4, 6.3 Tensile Strength ISO 1135-4, 5.3 Tensile Strength Additionally, flow rate accuracy testing using the proposed Hospira Sapphire Sets and the Sapphire Infusion System has been conducted. All testing is acceptable. The product Sterility Assurance Level is 10^{-6} .

Conclusion

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