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

June 1, 2016

Hospira, Inc.
Mr. David Blonski
Director Regulatory Affairs
375 Field Drive
D-393, Building H3
Lake Forest, Illinois 60045

Re: K160870
Trade/Device Name: Hospira Administration Sets: Hospira Primary Sets, Hospira Extension Sets, Hospira Burette Sets, and Hospira Blood Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: May 2, 2016
Received: May 3, 2016

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,

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

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)*
K160870

Device Name
Hospira Administration Sets: Hospira Primary Sets, Hospira Extension Sets, Hospira Burette Sets, Hospira Blood Sets

Indications for Use *(Describe)*
Hospira Primary 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.

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

Hospira Blood sets are indicated for the delivery of fluids including but not limited to blood and blood products from a container to a patients 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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510(k) Summary-K160870

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

Submitter Information	
Name	Hospira, Incorporated
Address	D-393, Bldg. H3 375 North Field Drive Lake Forest, IL. 60045
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	May 24, 2016
Name of device	
Trade or proprietary name	Hospira Administration Sets: Hospira Primary Sets, Hospira Extension Sets, Hospira Burette Sets, Hospira 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 Primary Sets – K142367 Hospira Primary Sets - K143015 Hospira Extension Sets – K142433 Hospira Extension Sets – K142974 Hospira Burette Sets - K142622 Hospira Blood Sets - K143087
Reason for 510(k) submission	Device modification adding an alternate luer activated needleless valve.
Device description	The subject of this Special 510(k): Device Modification is the addition of an alternate luer activated needleless valve to existing Hospira Administration sets cleared under the identified predicate 510(k)s. Hospira Administration Sets are comprised of components in various combinations of the following: male luer adapter with cap, female luer with cap, piercing pin connector, tubing, flow control device, filter, in-line adapter, injection site assembly, luer activated needleless valve Nuitiv™ Connector, check valve, burette chamber, and blood chamber. Hospira Administration Sets are intended for the delivery of fluids from a container to a patient's vascular system. Hospira Administration 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 Administration sets are intended for the delivery of fluids, including blood and blood products where indicated, from a container to a patient's vascular system.

Summary of the technological characteristics of the device compared to the predicate device							
Characteristic	**Predicates**						**Proposed Device**
	K142367	**K143015**	**K142433**	**K142974**	**K142622**	**K143087**	**K160870**
Indications for Use	Indications for Use: Hospira Primary sets are indicated for the delivery of fluids from a container to a patient's vascular system.	Indications for Use: Hospira Primary sets are indicated for the delivery of fluids from a container to a patient's vascular system.	Indications for Use: Hospira Extension sets are indicated for the delivery of fluids from a container to a patient's vascular system.	Indications for Use: Hospira Extension sets are indicated for the delivery of fluids from a container to a patient's vascular system.	Indications for Use: Hospira Burette sets are indicated for the delivery of fluids from a container to a patient's vascular system.	Indications for Use: 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.	Indications for Use: Hospira Primary sets are indicated for the delivery of fluids from a container to a patient's vascular system. Indications for Use: Hospira Extension sets are indicated for the delivery of fluids from a container to a patient's vascular system. Indications for Use: Hospira Burette sets are indicated for the delivery of fluids from a container to a patient's vascular system. Indications for Use: 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.
Design and Materials of Construction	The predicate component, the CLAVE ™ Connector is a luer activated needleless valve cleared under predicate 510(k) K142367 The CLAVE™ Connector consists of the following materials: Body: PBT - GE Valox 215 or Valox 315 Spike: MABS - Terlux 2812TR or Polycarbonate – Bayer Makrolon RX 2530-451118 Plug: Silicone – Wacker Elastosil LR 3003/70 Lubricant: Silicone, Dow, FS-1265	Same as K142367	Same as K142367	Same as K142367	Same as K142367	Same as K142367	The proposed alternate component, the Nuitiv™ Connector is a luer activated needleless valve. The Nuitiv™ Connector consists of the following materals: Body: Polycarbonate, Makrolon RX1805 Spike: Tritan MX731 copolyester Plug: Silicone – Wacker Elastosil LR3066/55 (gland) Lubricant: Silicone - Med400, nusil

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

Characteristic	Predicates						Proposed Device
	K142367	K143015	K142433	K142974	K142622	K143087	K160870
Summary of non-clinical tests for determination of substantial equivalence	Based on the design control activities, risk assessment and verification/validation testing for the subject device modifications the following performance bench tests were performed on the subject devices: All materials of construction for the predicate component CLAVE™ Connector meet the applicable material test requirements for ISO 10993 as demonstrated in the predicate 510(k).	Same as K142367	Same as K142367	Same as K142367	Same as K142367	Same as K142367	Based on the design control activities, risk assessment and verification/validation testing for the subject device modifications the following performance bench tests were performed on the subject devices: All materials of construction for the proposed component Nuitiv™ Connector 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 Subchronic Toxicity Pyrogenicity
Summary of Performance Testing	Performance testing for predicate component CLAVE™ Connector was conducted as indicated in the predicate 510(k) to ensure the device performs as intended in accordance with applicable standards. All testing is acceptable. The product Sterility Assurance Level is for Hospira Administration sets is 10^{-6}.	Same as K142367	Same as K142367	Same as K142367	Same as K142367	Same as K142367	Performance data has been generated for the proposed Nuitiv™ Connector in accordance with: ISO 594-1 Section 4.1.1 Gauging ISO 594-2 Section 4.2.1 Liquid Leakage Section 4.2.2 Air Leakage Section 4.3 Separation Force Section 4.4 Unscrewing Torque Section 4.5 Ease of Assembly Section 4.6 Resistance to Overriding Section 4.7 Stress Cracking ISO 8536-4 Section 6.1 Particulate Matter Section 6.2 Air Leakage Section 6.3 Tnsile Strength ISO 8536-8 Section A.3.2 Air Leakage Section A.3.3 Air Leakage Section A.3.4 Liquid Leakage ISO 1135-4 Section 5.1 Particulate Matter Section 5.2 Air Leakage Section 5.3 Tensile Strength All testing is acceptable. The product Sterility Assurance Level is 10^{-6}.

Conclusion

The proposed alternate component Nuitiv™ Connector in the subject devices meets the functional claims and intended use as described in the product labeling. The proposed component Nuitiv™ Connector in the subject devices is substantially equivalent to the predicate device component CLAVE™ Connector.