510(k) SUMMARY

AUG 11 2010

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

Submitter Information [21 CFR 807.929(a)(1)]	
Name	Hospira Incorporated
Address	D-389, Bldg H2, 375 N. Field Drive, Lake Forest, Illinois 60045
Phone number	224-212-5316
Fax number	224-212-5401
Establishment Registration Number	9063339
Name of contact person	Karen Keener
Date prepared	July 20, 2010
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	*Hospira PVC Infusion Blood Set*
Common or usual name	Fluid delivery tubing
Classification name	Sets, Administration, Intravascular
Classification panel	General Hospital
Regulation	880.5440
Product Code(s)	FPA
Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]	Hospira Infusion Blood sets utilize components from various Hospira Infusion set families; including but not limited to: Lifeshield Latex-Free Veniloop Connector with Prepierced Injection Site, Non-DEHP (K063239) Lifeshield Latex-Free Plum Non-Vented Blood set (K030002) HEMA Y-Type Transfusion Blood Filter Pump Set 100 Inch-SL with Prepierced Reseals (Latex-Free) (K780880)
Reason for 510(k) submission	To offer a non-DEHP PVC alternative Infusion set with a manual blood pump.
Device description [21 CFR 807.92(a)(4)]	The Hospira PVC Infusion Blood Sets with/without the Manual blood pump consists of Non-DEHP PVC tubing and components previously cleared in Hospira 510k's. The change addressed in this submission, is the material used to construct the cylindrical blood pump. The modified design incorporates a ball check valve previously used in the bulb style manual blood pump. Other changes include minor dimensional and geometric changes.
Intended use of the device [21 CFR 807.92(a)(5)]	Hospira 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.

Performance Data [21 CFR 807.92(b)]

Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]

Performance Test Summary-New Device

Characteristic	Standard/Test Method	Standard / Test Title	Device Performance
Biocompatibility	ISO 10993-5: 2009	Cytotoxicity	Pass
Biocompatibility	ISO 10993-10: 2002	Sensitization	Pass
Biocompatibility	ISO 10993-10: 2002	Irritation / Intracutaneous Reactivity	Pass
Biocompatibility	ISO 10993-11:2006	Systemic Toxicity (Acute)	Pass
Biocompatibility	ISO 10993-4:2002	Hemocompatibility	Pass
SAL 10^{-6}	ISO 11137-2:2006	Sterility	Pass
Packaging Particulate Bond Strength Piercing function Flow characteristics Specific Required Physical Characteristics	ISO 1135-4:2004	Transfusion Equipment for Medical Use	Pass
Gravity Set Characteristics	8536-4:2004	Infusion Equipment for Medical Use; Part 4.	Pass
Dimensional Conformance and Connection compatibility	ISO 594-2	Conical Fittings with a 6% (Luer) Taper for syringes, needles, and certain other equipment	Pass

Summary Discussion of Bench Performance Data

The Hospira Blood administration sets with 200-micron filter and Non-DEHP PVC manual blood pump passed all specified test requirements.

The validation and verification testing confirmed product meets user needs and design inputs for an administration set containing a manual blood pump.

Testing also confirmed physical attributes and device performance meet requirements of the standards listed in the 'Performance test summary" above. These standards address sterility, biocompatibility, particulate, leakage, tensile strength, filter characteristics, drip tube performance, flow control, and simulated actual conditions of use.

Summary of clinical tests conducted for determination of substantial equivalence or of clinical information [21 CFR 807.92(b)(2)]
Not required. Bench testing can adequately address the safety and efficacy of this product.
Statement of Safety and Efficacy [21 CFR 807.92]
The Hospira Infusion Blood Sets with/without Manual Blood Pump meet the functional claims, and intended use as described in the product labeling. The safety and effectiveness are equivalent to the predicate Hospira Administration Blood Sets with Manual Blood Pump. The claim for substantial equivalence is supported by the information provided in the 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Karen Keener
Global Regulatory Associate
Hospira, Incorporated
375 North Field Drive
Lake Forest, Illinois 60045

Re: K101677

AUG 11 2010

Trade/Device Name: Hospira Infusion Blood Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: July 29, 2010
Received: July 30, 2010

Dear Ms. Keener:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Susan Runner

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5: Indications for Use

AUG 11 2010

510(k) Number (if known) K101677

Device Name: Hospira Infusion Blood Sets

Indications for Use: Hospira Administration sets are intended for the delivery of fluids including but not limited to blood and blood products from a container into a patients vascular system.

Prescription Use X **AND/OR** **Over –The- Counter Use** ___
(Part 21 CFR 801 Subpart D) **(Part 21 CFR *)& Subpart C)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101677