K103344

Infusion Set Modification **November 12, 2010**
Special 510(k)

DEC 10 2010

Section 6: 510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92. Hospira Infusion Sets with alternate fixed diaphragm Back Check Valve

Submitter Information	
Name	Rebecca Andersen
Address	275 North Field Drive
Phone number	224-212-5270
Fax number	224-212-5401
Establishment Registration Number	Owner/Operator #9063339
Name of contact person	Rebecca Andersen
Date prepared	November 12, 2010
Name of device	
Trade or proprietary name	Hospira Infusion Sets
Common or usual name	IV Set
Classification name	Infusion Sets Class II
Classification panel	80-FPA – General Hospital
Regulation	21 CFR Part 880.5440
Product Code(s)	80-FPA
Legally marketed device(s) to which equivalence is claimed	Symbiq sets as cleared in K041550
Reason for 510(k) submission	Back Check Valve component
Device description	Hospira infusion sets are intended for use as gravity sets or with dedicated Hospira Infusion Pumps. Hospira infusion sets are disposable devices for single patient use, which incorporate various set configurations and components. These components including the back check valve which is the subject of this submission may be shared across Hospira set families and used with sets designed for gravity or other pump platforms.
Intended use of the device	Infusion sets are intended for the delivery of fluids, solutions, drugs, agents, nutritionals, electrolytes, blood and blood products via parenteral, enteral, intravenous, intra-arterial, subcutaneous, epidural or irrigation routes of administration. These sets are intended for use primarily in the hospital setting and can be used in other acute and non-acute care areas, such as, but not limited to Home Care, Nursing Homes, Mobile Intensive Care, Ambulatory Infusion Centers, Hospice, Subacute facilities, Outpatient / Surgical Centers, Long Term Care, Urgent Care, Transport and in Physician offices.
Indications for use	These are general use sets which are intended for use primarily in the hospital setting and can be used in other acute and non-acute care areas, such as, but not limited to Home Care, Nursing Homes, Mobile Intensive Care, Ambulatory Infusion Centers, Hospice, Subacute facilities, Outpatient / Surgical Centers, Long Term Care, Urgent Care, Transport and in Physician offices.

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

Characteristic	Proposed Device Hospira Infusion Set	Predicate Symbiq Infusion Set K041550
Intended Use	Same	These sets are intended for use primarily in the hospital setting and can be used in other acute and non-acute care areas, such as, but not limited to Home Care, Nursing Homes, Mobile Intensive Care, Ambulatory Infusion Centers, Hospice, Subacute facilities, Outpatient / Surgical Centers, Long Term Care, Urgent Care, Transport and in Physician offices.
Set Functionality	Same	Meets all performance V&V testing
Visual characteristics	Similar Back Check valve is of similar size, but is **blue** and **clear**	Back check valve is clear / **white**
Back Check Valve	Normally closed - One way check valve in two piece housing with **fixed** silicone diaphragm	Normally closed - One way check valve in two piece housing with **floating** silicone diaphragm
Bonding processes	Same	Solvent bond / over post or socket bond
Biocompatibility	Same	External Communicating - Blood path indirect –Prolonged contact
Principle of Operation	Same	One way pressure differential

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

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

Summary discussion of Bench Performance Data

The Hospira Infusion sets with an alternate Back Check Valve passed all specified test requirements. Tests demonstrate excellent performance with respect to reduction of backflow. The validation and verification testing confirmed these devices meet user needs and design inputs for an Infusion set.

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, leakage, and tensile strength.

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CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

Statement of Safety and Efficacy:

The Hospira Infusion Sets with the alternate back check valve meet the functional claims, and intended use as described in the product labeling. The safety and effectiveness, are substantially equivalent to the predicate Hospira Infusion Sets as cleared in K041550

The claim for substantial equivalence is supported by the information provided in this Special 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. Rebecca Anderson
Associate Director, Global Regulatory Affairs, Devices
HOSPIRA, Incorporated
275 North Field Drive
Lake Forest, Illinois 60045

DEC 10 2010

Re: K103344
Trade/Device Name: Hospira Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: November 12, 2010
Received: November 15, 2010

Dear Ms. Anderson:

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.

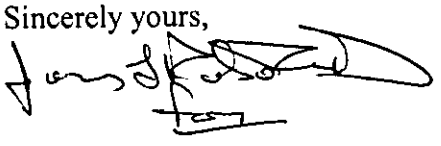
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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

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Section 5: Indications for Use

510(k) Number (unknown at this time)

Device Name: Hospira Infusion Set

Infusion sets are intended for the delivery of fluids, solutions, drugs, agents, nutritionals, electrolytes, blood and blood products via parenteral, enteral, intravenous, intra-arterial, subcutaneous, epidural or irrigation routes of administration. These sets are intended for use primarily in the hospital setting and can be used in other acute and non-acute care areas, such as, but not limited to Home Care, Nursing Homes, Mobile Intensive Care, Ambulatory Infusion Centers, Hospice, Subacute facilities, Outpatient / Surgical Centers, Long Term Care, Urgent Care, Transport and in Physician offices.

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

Richard C. Chapman 12/10/10

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

510(k) Number: K103344