K110901

510(k) SUMMARY
Safety and Effectiveness

MAR - 5 2012

Submitter Information	
Name	Hospira, Inc.
Address	275 North Field Dr, Lake Forest, IL 60045
Phone number	224-212-4897
Fax number	224-212-5401
Establishment Registration Number	3005579246
Name of contact person	Ray Silkaitis/Yuliya Matlin
Date prepared	03/05/2012
Name of device	
Trade or proprietary name	Symbiq™ Infusion System
Common or usual name	Infusion Pump and Administration sets
Classification name	Infusion Pump /Administration Sets
Classification panel	80
Regulation	880.5725 and 880.5440
Product Code(s)	FRN and FPA
Legally marketed device(s) to which equivalence is claimed	Hospira Phoenix Infusion System with Hospira MedNet Software, cleared under K041550 on 06/30/2004
Reason for 510(k) submission	Cumulative changes
Device description	Symbiq™ Infusion System includes a volumetric piston-driven infusion pump and utilizes dedicated disposable administration sets for fluid delivery to the patient. The pump's plunger cyclically pressurizes the administration set's cassette pumping chamber through an elastomeric diaphragm to deliver fluid. The device has a touchscreen user interface to program various therapies. At low flow rates the infusion pump is designed to maintain low flow continuity. The infusion pump utilizes drug safety software to set hospital drug dosing parameters. The system can communicate wired or wirelessly over the hospitals network infrastructure through Hospira MedNet™ server software with Hospital Information Systems. The pump is available in one-channel and two-channel configurations.
Intended use of the device	Symbiq™ Infusion System is intended for the delivery of fluids, solutions, drugs, agents, nutritional, electrolytes, blood and blood products via parenteral, enteral, intravenous, intra-arterial, subcutaneous, epidural or irrigation routes of administration. It is intended primarily for use the hospital setting and can be used in other acute and non-acute care areas outside of the hospital under the supervision of the healthcare provider. All data entry and validation of infusion parameters is performed by a trained healthcare professional according to physician's orders.

Indications for use	The Symbiq™ Infusion System is 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. It is intended primarily for use in the hospital setting and can be used in other acute and non-acute care areas, such as, but not limited to Nursing Homes, Mobile Intensive Care, Ambulatory Infusion Centers, Hospice, Subacute Facilities, Outpatient/Surgical Centers, Long Term Care, Urgent Care, Transport and Physician Offices.

Summary of the technological characteristics of the device compared to the predicate device			
Device Name	**Predicate Device** Hospira Phoenix Infusion System with Hospira MedNet™ Software K041550		**Subject Device** Symbiq™ Infusion System
Pump Type	Volumetric Piston Type		Same
Number of dosing units	66		91
Basic Dosing Units	ng/kg/min mcg/kg/min mcg/kg/hr mcg/min mcg/hr mg/kg/hr mg/min mg/hr	grams/hr U/kg/hr U/min U/hr mUn/min mEq/hr mL/hr	Same
Routes of Administration	Parenteral, Intravenous, Arterial, Enteral, Subcutaneous, Epidural, Irrigation		Same
Free Flow Protection	Administration set and pump based free flow protection features		Same
Drug Library Feature	Yes		Same
Drug Alerts	Soft and Hard Limits		Same
Power Source	AC: 100-240 VAC and rechargeable lithium ion battery		Same
Battery Life	With a fully charged battery, both one-channel and two-channel infusers deliver four hours of operation at 125 mL/hr with the LCD backlight set to the Power Saving mode		Same
Display	8.4 in. diagonal; Color LCD		Same
Physical characteristics One Channel pump	Width: 9.9 in. Height: 10.2 in. Depth: 8.6 in. Depth with pole clamp: 13 in. Weight: 10.7 lbs. Casing: High-impact plastic		Similar Depth increased 1.7 in to add a pole alignment guide

Summary of the technological characteristics of the device compared to the predicate device		
Device Name	**Predicate Device** Hospira Phoenix Infusion System with Hospira MedNet™ Software K041550	**Subject Device** Symbiq™ Infusion System
Physical characteristics Two channel pump	Width: 10.9 in. Height: 10.2 in. Depth: 8.6 in. Depth with pole clamp: 13 in. Weight: 12.1 lbs. Casing: High-impact plastic	Similar Depth increased 1.7 in to add a pole alignment guide
Low Flow continuity	Yes with Microbore sets	Same
Accuracy	± 5% for rates > 1 mL/hour. ± 10% for rates <=1 mL/hour	± 5% at all rates
Delivery Rate Ranges	• 0.1 to 99.9 mL/hr (in 0.1 mL increments) • 100 to 1000 mL/hr (in 1 mL increments)	Same
VTBI (Volume to be Infused) Ranges	• 0.1 to 99.9 mL (in 0.1 mL increments) • 100 to 9999 mL (in 1 mL increments)	Same
Occlusion Settings	• Distal: User specified range in either psi (from 1 to 15 in increments of 0.5) or mmHg (from 50 to 775 in increments of 25) • Proximal: -5 psi/250 mmHg	Same
Primary Alarms conditions	Check Cassette, Proximal Occlusion, Distal Occlusion, Air-in-line, Low Battery, Depleted Battery, Service Battery, Power Loss, Callback, End of Infusion, Emergency Stop, Nearing End of Infusion	Same

PERFORMANCE DATA

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

Performance Test Summary-New Device

System verification and validation activities for Symbiq™ Infusion System confirmed that the system meets user needs and design inputs. All the testing met the acceptance criteria.

Risk management activities are incorporated in to the design and development process and a Safety Assurance Case has been generated to demonstrate the safety of the Symbiq™ Infusion System.

Risk management as well as verification and validation activities incorporate the principles of applicable FDA guidance such as *"Total Product Life Cycle: infusion Pump –Premarket Notification [510(k)] Submissions (DRAFT GUIDANCE)"* issued in April 23, 2010 and *"General Principles of Software Validation; Final Guidance for Industry and FDA Staff,"* issued January 11, 2002. Human Factors studies have been conducted to validate the effectiveness of use related error mitigations.

Characteristic	Standard/Test/FDA Guidance	Results Summary
Electrical and Mechanical Safety	IEC 60601-1 (1988): Medical electrical equipment – Part 1: General requirements for safety, including Amendment 1 (1991) and Amendment 2 (1995) for Type B equipment	Pass
Electromagnetic Compatibility	IEC 60601-1-2 (2001): Medical Electrical Equipment, Part 1-2: General Requirements for Safety, Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	Pass
Alarm Systems	IEC 60601-1-8 Ed.1 (2003-08) Part 1-8: General requirements for safety – Collateral standard: Alarm systems	Pass
Sets Biocompatibility	ISO 10993-1:2009: Biological Evaluation of Medical Devices Part 1: Evaluation and Testing	Pass

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical evaluations and human factors studies have been conducted for the Symbiq™ Infusion System. The Human Factors Use Safety Validation study showed that there were no instances of participants failing to complete tasks correctly during the study. The sum of clinical evaluation and human factors testing support the safety and effectiveness of Symbiq™ Infusion System.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The results of the verification and validation testing with the results of human factors and clinical evaluations performed supported by static analysis of the software code and the Safety Assurance Case demonstrate that the modifications described in the submission do not introduce any additional issues of safety and effectiveness. The subject device is substantially equivalent to the predicate.

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

Dr. Ray Silkaitis
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Hospira, Inc.
275 North Field Drive
Lake Forest, Illinois 60045

MAR - 5 2012

Re: K110901
Trade/Device Name: Symbiq™ Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN, FPA
Dated: February 28, 2012
Received: February 29, 2012

Dear Dr. Silkaitis:

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 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

Indications for Use

510(k) Number (unknown at this time)

Device Name: **Symbiq™ Infusion System**

Indications for Use:

The Symbiq™ Infusion System is 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.

It is intended primarily for use in the hospital setting and can be used in other acute and non-acute care areas, such as, but not limited to Nursing Homes, Mobile Intensive Care, Ambulatory Infusion Centers, Hospice, Subacute Facilities, Outpatient/Surgical Centers, Long Term Care, Urgent Care, Transport and Physician Offices.

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)

3/5/12

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

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