Primary Symbiq ™ Set, MICRODRIP™, Piggyback with Backcheck Valve, 2 CLAVE™ Y-Sites, Distal Microbore Tubing, 0.2 Micron Filter, 105 Inch, Non-DEHP, List Number 16120

Section 6: 510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92 for Primary Symbiq ™ Set, MICRODRIP™, Piggyback with Backcheck Valve, 2 CLAVE™ Y-Sites, Distal Microbore Tubing, 0.2 Micron Filter, 105 Inch, Non-DEHP, List Number 16120 is provided below.

Submitter Information	
Name	Hospira, Incorporated
Address	275 North Field Drive Lake Forest, IL 60045
Phone number	224-212-4857
Fax number	224-212-5401
Establishment Registration Number	3005579246
Name of contact person	Yuliya Matlin, M.S., M.B.A
Date prepared	May 23, 2012
Name of Device	
Trade or proprietary name	Primary Symbiq™ Set, MICRODRIP™, Piggyback with Backcheck Valve, 2 CLAVE™ Y-Sites, Distal Microbore Tubing, 0.2 Micron Filter, 105 Inch, Non-DEHP, List Number 16120, part of Symbiq Infusion System
Common or usual name	Infusion Pump and Administration Sets
Classification name	Infusion Pump and Intravascular Administration Set
Classification panel	General Hospital
Regulation	21-CFR Part 880.5725 and 21-CFR Part 880.5440
Product Code(s)	80-FRN, 80-FPA
Legally marketed device(s) to which equivalence is claimed	Primary Symbiq™ Set , MICRODRIP™, Piggyback with Backcheck Valve, 2 CLAVE™ Y-Sites, Distal Microbore Tubing, 0.2 Micron Filter, 105 Inch, Non-DEHP, List Number 16120 as cleared in K110901 on March 5, 2012.
Reason for 510(k) submission	Labeling updates to reflect the qualifications of Hospira List Number 16120 for use at flow rates between 100 ml/hr and 500 ml/hr.
Device description	List Number 16120 is a Primary Symbiq™ set that includes MICRODRIP™ Drop Former, Sight Chamber, Backcheck Valve, 2 CLAVE™ Y-Sites, Distal Microbore Tubing, 0.2 Micron Filter, 105 Inch and is non-DEHP . It is designed specifically for use with the Symbiq™ Infusion Pump and is used to administer fluids from a container to a patient's vascular system though a needle or catheter. The set has a sterile fluid pathway and is for single patient use.

Primary Symbiq ™ Set, MICRODRIP™, Piggyback with Backcheck Valve, 2 CLAVE™ Y-Sites, Distal Microbore Tubing, 0.2 Micron Filter, 105 Inch, Non-DEHP, List Number 16120

Intended use of the device	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. They are 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

Characteristic	Subject Device	Predicate
Intended use	Same	Same
Set Functionality/Principal of Operation	Same	Same
Components	Same	Same
Biocompatibility	Same	Same
Sterilization	Same	Same
Flow rate qualification of List Number 16120	0.1ml/hr to 500 ml/hr	0.1 ml/hr to 100ml/hr
Delivery accuracy of List Number 16120 at flow rates between 0.1ml/hr and 100 ml/hr under standard conditions	Same	Same
Delivery accuracy of List Number 16120 at flow rates between100ml/hr and 500ml/hr under standard conditions	+/- 10%	N/A

Summary of Non-Clinical Tests Conducted for Determination of Substantial Equivalence

Performance Test Summary – New Device

Characteristic	Test Method	Test Title	Device Performance
Delivery Accuracy at Flow Rate of 500ml/hr	System Verification	System Accuracy Performance	Pass

Summary Discussion of Bench Performance Data

The subject device met all the acceptance criteria and the accuracy performance claims under standard conditions as described in product labeling. Device performance meets the requirements of the testing listed in the "Performance Test Summary – New Devices" table above. The subject device is identical to the predicate with the exception of the label.

Statement of Safety and Efficacy

The subject device meets the accuracy claims and intended use as described in the product labeling. The safety and effectiveness are substantially equivalent to the predicate Primary Symbiq™ Set, MICRODRIP™, Piggyback with Backcheck Valve, 2 CLAVE™ Y-Sites, Distal Microbore Tubing, 0.2 Micron Filter, 105 Inch, Non-DEHP, List Number 16120 as cleared in K110901 on March 5, 2012. 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. Yuliya Matlin, M.S., M.B.A.
Associate Director
Hospira, Incorporated
275 North Field Drive
Lake Forest, Illinois 60045

JUN 2 1 2012

Re: K121032
Trade/Device Name: Primary Symbiq™ Set MICRODRIP™ Piggyback with Backcheck Valve, 2 CLAVE™ Y-Sites, Distal Microbore Tubing, 0.2 Micron Filter 105 Inch, Non-DEHP, List Number 16120
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: May 23, 2012
Received: May 24, 2012

Dear Ms. Matlin:

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.

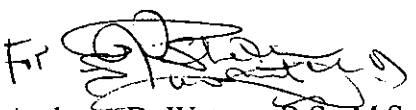
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

K121032

510(k) Number

Device Name: **Primary Symbiq™ Set, MICRODRIP™, Piggyback with Backcheck Valve, 2 CLAVE™ Y-Sites, Distal Microbore Tubing- 0.2 Micron Filter, 105 Inch, Non-DEHP, List Number 16120**

Indications for Use:

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. They are 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, Sub acute 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)

Division Sign-Off)
ivision of Anesthesiology, General Hospital
ifection Control, Dental Devices

510(k) Number: K121032