K090882

5 510(k) SUMMARY

APR 2 3 2010

5.1 Submitted by:

Hospira, Inc.
D-389 Bldg. H2
275 N. Field Drive
Lake Forest, IL 60045

Phone: (224)212-4898
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Contact: Keith Dunn

5.2 Date Prepared: March 25, 2009

5.3 Name/Classification of Device: **Saline, Vascular Access Flush,** Intravascular, Catheter, Class 2, 80-NGT

5.4 Trade Name of Proposed Device: 0.9% Sodium Chloride Flush Syringe

5.5 Predicate Devices:

Device Name	510(k) Number
Modification to Syringe Pre-filled with 0.9% Sodium Chloride	K001616
Syringe Pre-filled with 0.9% Sodium Chloride	K953805
Modification to Monoject Pre-Fill 0.9% Sodium Chloride	K032438

5.6 Proposed Device Description:

The proposed Flush Syringe pre-filled with 0.9% Sodium Chloride will be composed of a medical grade plastic syringe and 0.9% Sodium Chloride for the purpose of flushing and assessing the patency of indwelling catheters and venipuncture devices

5.7 Statement of Intended Use:

For the flushing and assessing the patency of indwelling catheters and venipuncture devices which are designed for intermittent injection therapy, blood sampling, or fluid and nutritional therapy.

5 510(k) SUMMARY (continued)

5.8 Summary of Technological Characteristics of New Device Compared to Predicate Devices:

The Flush Syringe pre-filled with 0.9% Sodium Chloride as described in this submission is substantially equivalent to the predicate Flush Syringe pre-filled with 0.9% Sodium Chloride with respect to the following characteristics:

5.8.1 Similarities:

- Both devices are intended to be used to flush or assess the patency of indwelling catheters and venipuncture devices
- The technology and operating principles are the same for both devices
- The fill size of the syringe

5.8.2 Differences:

- The sterilization method
- The plunger tip material and shape

The claim for substantial equivalence is supported by the information provided in this 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

Mr. Keith Dunn
Manager
Hospira, Incorporated
275 North Field Drive, D-389, Building, H2
Lake Forest, Illinois 60045

APR 23 2010

Re: K090882
Trade/Device Name: Flush Syringe Filled with 0.9% Sodium Chloride
Regulation Number: 21 CFR 880.5200
Regulation Name: Saline, Vascular Access Flush
Regulatory Class: II
Product Code: NGT
Dated: April 12, 2010
Received: April 13, 2010

Dear Mr. Dunn:

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.

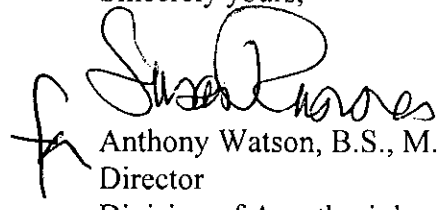
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Device Name: Flush Syringe filled with 0.9% Sodium Chloride

List Numbers/Descriptions: 1078-10 30 x 10mL single use syringes, 1078-20 100 x 10mL single use syringes, 1078-25 30 x 5mL single use syringes, 1078-35 100 x 5mL single use syringes, 1078-23 30 x 3mL single use syringes, and 1078-33 100 x 3mL single use syringes.

Indications for Use:

For the flushing and assessing the patency of indwelling catheters and venipuncture devices which are designed for intermittent injection therapy, blood sampling, or fluid and nutritional therapy.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K090151