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K011967

JAN 2 3 2002

BD

Indispensable to human health

Summary of Safety and Effectiveness for the Heparin Lock Flush Solution, USP BD Pre-Filled Heparin Lock Flush Syringe

1 BD Contact person:

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BD Medical Surgical – Mail Code 226
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Phone (201) 847-4344
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2 Device Name: Heparin Lock Flush Solution, USP
BD Pre-Filled Heparin Lock Flush Syringe

3 Predicate Device(s):

3.1 Vital Signs Heparin Lock Flush Device K953120
3.2 BD Preefil™ Normal Saline Flush Syringe K982558
3.3 Baxter Heparin Lock Flush Syringe K003245

4 Product Description / Function:

Product sizes/reorder numbers: The following sizes/reorder numbers of the Heparin Lock Flush Solution, USP syringes to be offered are:

BD Cat. #	Description
306509	Heparin, 10u/mL, 6mL Fill In 10mL Syringe
306510	Heparin, 10u/mL, 5mL Fill In 10mL Syringe
306511	Heparin, 10u/mL, 5mL Fill In 5mL Syringe
306521	Heparin, 10u/mL, 3mL Fill In 10mL Syringe
306512	Heparin, 10u/mL, 3mL Fill In 3mL Syringe
306527	Heparin, 10u/mL, 2mL Fill In 3mL Syringe
306513	Heparin, 100u/mL, 5mL Fill In 10mL Syringe
306514	Heparin, 100u/mL, 3mL Fill In 10mL Syringe

BD Cat. #	Description
306515	Heparin, 100u/mL, 5mL Fill In 5mL Syringe
306516	Heparin, 100u/mL, 3mL Fill In 5mL Syringe
306517	Heparin, 100u/mL, 3mL Fill In 3mL Syringe
306528	Heparin, 100u/mL, 2mL Fill In 3mL Syringe
306525	Heparin, 10u/mL, 5mL Fill In 10mL Syringe With Blunt Plastic Cannula
306531	Heparin, 100u/mL, 5mL Fill In 10mL Syringe With Blunt Plastic Cannula
306529	Heparin, 100u/mL, 5mL Fill In 5mL Syringe With Blunt Plastic Cannula
306537	SASH Kit (2 - 0.9% Sodium Chloride Syringes and 1 - 100u/mL Heparin Lock Flush Syringe), 5mL Fill In 10mL Syringe - 100u/mL Heparin
306538	SASH Kit (2 - 0.9% Sodium Chloride Syringes and 1 - 10u/mL Heparin Lock Flush Syringe), 3mL Fill In 3mL Syringe - 10u/mL Heparin
306539	SASH Kit (2 - 0.9% Sodium Chloride Syringes and 1 - 100u/mL Heparin Lock Flush Syringe), 3mL Fill In 5mL Syringe - 100u/mL Heparin

Intended Uses: Heparin Lock Flush Solution, USP syringes are intended for use in maintaining patency of vascular access devices (VAD'S).

5 Equivalence determination:

The elements of comparison between the Heparin Lock Flush Solution, USP syringes with the BD Preefil™ Normal Saline Flush syringe, the Baxter Heparin Lock Flush syringe and Vital Signs Heparin Lock Flush Device predicate devices are as follows:

- The Heparin Lock Flush Solution, USP syringe contains sterile flush (0.9% Sodium Chloride Injection, USP and Heparin Sodium 10 and 100U/mL solution as does the predicate devices).
- The Heparin Lock Flush Solution, USP syringe has a sterile solution contents and fluid path as do the predicate devices.
- The Heparin Lock Flush Solution, USP syringe is aseptically filled as the predicate device, BD Preefil™.
- The Heparin Lock Flush Solution, USP syringe is a three-piece piston design as are the predicate devices, BD Preefil™and the Baxter Heparin Lock Flush syringe.
- The Heparin Lock Flush Solution, USP syringe barrel is molded from polypropylene as are the predicate devices, BD Preefil™and the Baxter Heparin Lock Flush syringe.
- The Heparin Lock Flush Solution, USP syringe has a similar package unit design as the predicate device, BD Preefil™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2002

Mr. Gregory W. Morgan
BD Medical Surgical
BD Medical Injections Systems
1 Becton Drive, MC 226
Franklin Lakes, New Jersey 07417

Re: K011967
Trade/Device Name: BD Pre-Filled Heparin Lock Flush Syringe
Regulation Number: 880.5200
Regulation Name: Heparin Lock Flush Syringe
Regulatory Class: II
Product Code: NGT
Dated: November 7, 2001
Received: November 8, 2001

Dear Mr. Morgan:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011967

Indications for Use

The Heparin Lock Flush Solution, USP syringes are intended for use in maintaining patency of vascular access devices (VAD'S).

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