AUG 2 6 2004

K042061

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510K SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Submitted By:**

Peter Zurlo
Manager, Regulatory Affairs

B D Medical Surgical
1 Becton Drive
Franklin Lakes, NJ 07417-1883

Phone: 201-847-6447
Fax: 201-847-4855

2. **Device Name:**

Trade Name: 0.9% Sodium Chloride Injection, USP-
BD Posiflush SF Flush Syringe

Common Name: Saline Flush Syringe

Classification Name: Device, Flush, Vascular Access

3. **Predicate Device:**

0.9% Sodium Chloride Injection, USP-
BD Posiflush SP Pre-filled Flush Syringe

Manufactured by: Becton Dickinson and Company

4. **Device Description:**

The Predicate Device, the 0.9% Sodium Chloride Injection, USP- BD Posiflush SP Pre-Filled Flush Syringe (510(k) Number: K003553) is a single use disposable Hypodermic syringe filled with 0.9% Sodium Chloride Injection, USP and is intended for use in maintaining patency of vascular access devices (VAD's).
The Predicate Device is only fluid path sterile to SAL of 10^{-6}.

The Modified Device, the subject of this 510(k), the 0.9% Sodium Chloride Injection, USP BD Posiflush SF Pre-Filled Flush Syringe was modified by changing the current individual package wrap to a package that is capable of being sterilized and will maintain sterility of the exterior of the device. This will allow the device to be used on sterile field applications.
The Modified Device is manufactured of the same materials, has the same intended use and SAL of 10^{-6} as the Predicate Device.

5. **Intended Use:**

Same intended use as the Predicate Device.
The 0.9% Sodium Chloride Injection, USP, BD Posiflush SF Flush Syringes is intended for use in maintaining patency of vascular access devices (VAD's).

Technological Characteristics:

The Modified Device, the subject of this 510(k), the 0.9% Sodium Chloride Injection, USP BD Posiflush SF Pre-Filled Flush Syringe was modified by changing the current individual package wrap to a package that is capable of being sterilized and will maintain sterility of the exterior of the device. This will allow the device to be used on sterile field applications.
The Modified Device is manufactured of the same materials, has the same intended use and SAL of 10^{-6} as the Predicate Device.

6. **Performance:**

Design Verification tests were performed based on the risk analysis performed and the results of these tests demonstrate that the BD Posiflush SF Flush Syringe performed in an equivalent manner to the predicate device and is safe and effective when used as intended.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E, under which a device can be marketed without pre-approval or classification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 6 2004

Becton Dickinson
C/O Mr. Peter Zurlo
Manager, Regulatory Affairs
BD Medical Surgical
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K042061
Trade/Device Name: 0.9% Sodium Chloride Injection, USP, BD Posiflush SF Flush Syringe
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: NGT
Dated: July 29, 2004
Received: August 2, 2004

Dear Mr. Zurlo:

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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
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 Statement

510(k) Number (if known): K042061

Device Name: 0.9% Sodium Chloride Injection, USP, BD Posiflush SF Flush Syringe

Indications for Use: The 0.9% Sodium Chloride Injection, USP, BD Posiflush SF Flush Syringes are intended for use in maintaining patency of vascular access devices (VAD's).

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801. 109)

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

510(k) Number: K042061