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JUL 1 7 2001

K011982

BD
Indispensable to human health

Summary of Safety and Effectiveness for the 0.9% Sodium Chloride Injection, USP BD Pre-Filled Flush Syringe

1 BD Contact person:

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Head of Regulatory Compliance
BD Medical Surgical – Mail Code 226
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2 Device Name: 0.9% Sodium Chloride Injection, USP BD Pre-Filled Flush Syringe

3 Predicate Device(s):

3.1 BD Preefil™ Normal Saline Flush Syringe K982558

4 Intended Uses: 0.9% Sodium Chloride Injection, USP BD Pre-Filled Flush Syringes are intended for use in maintaining patency of vascular access devices (VAD'S).

5 Device Description and Comparison: **(REVISED)**

A comparison between the new 0.9% Sodium Chloride Injection, USP BD Pre-Filled Flush Syringe and the existing BD Preefil Normal Saline Flush Syringe is provided in the table below:

Component/ Characteristic	**0.9% Sodium Chloride Injection, USP BD Pre-Filled Flush Syringe**	**BD Preefil Normal Saline Flush Syringe**
Barrel, Plunger Rod, Tip cap	Polypropylene	Polypropylene
Lubricant	Medical Grade Silicone	Medical Grade Silicone
Plunger Tip (stopper)	Latex Free Synthetic Rubber	Latex Free Synthetic Rubber
Syringe Tip	Luer Lok	Luer Lok
Saline Solution	0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP
Process	Aseptic Fill	Aseptic Fill

6 Equivalence determination:

The 0.9% Sodium Chloride Injection, USP BD Pre-Filled Flush Syringe has the following similarities to the predicate BD Preefil Normal Saline Flush Syringe:

- Same syringe components
- Syringes have the same operating principle
- Syringes have the same performance specifications
- Syringes have the similar design
- The saline solution in each product is identical
- The syringes have the same claims, including shelf life
- The syringes have the same packaging

In summary, the 0.9% Sodium Chloride Injection, USP BD Pre-Filled Flush Syringe described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2001

Mr. Gregory W. Morgan
Head of Regulatory
BD Medical Surgical
One Becton Drive MC226
Franklin Lakes, New Jersey 07417

Re: K011982
Trade/Device Name: 0.9% Sodium Chloride Injection, USP
BD Pre-Filled Flush Syringe
Regulation Number: 880.5200
Regulatory Class: II
Product Code: FOZ
Dated: June 25, 2001
Received: June 26, 2001

Dear Mr. Morgan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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

Attachment 2

Indications for Use Statement

510(k) Number: not known at this time

Device Name: 0.9% Sodium Chloride Injection, USP BD Pre-Filled Flush Syringe

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

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

510(k) Number K011982