K984590

OCT 7 1999

510(k) SUMMARY

Submitted by:

Marcia Marconi
Baxter Healthcare Corporation
I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:
December 24, 1998

Proposed Device:
The proposed device consists of various sizes and fill volumes of plastic syringes aseptically filled with sterile 0.9% sodium chloride solution.

Predicate Device:
The predicate device is the Abbott prefilled syringe with 0.9% sodium chloride solution.

Proposed Device Description:
The proposed device consists of various sizes and fill volumes of plastic syringes aseptically filled with sterile 0.9% sodium chloride solution.

Statement of Intended Use:

The device is intended for use in flushing compatible intravenous tubing systems and indwelling intravascular access devices.

Summary of Technological Characteristics of New Device Compared to Predicate Devices

The proposed device has the same technological characteristics as the predicate device. Both consist of plastic syringes containing sterile 0.9% sodium chloride solution.

Discussion of Nonclinical Tests; Conclusions Drawn from Nonclinical Tests

Test data have been generated for stability and container/closure suitability. Performance testing indicates that the proposed device meets or exceeds all functional requirements and supports its suitability for use.

DEC 24 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 1999

Ms. Marcia Marconi
Vice President, Regulatory Affairs
I.V. Systems Division
Regulatory Affairs
Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Re: K984590
Trade Name: 0.9% Sodium Chloride Flush Syringe
Regulatory Class: II
Product Code: FOZ
Dated: July 29, 1999
Received: August 2, 1999

Dear Ms. Marconi:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (21 CFR 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/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

510(k) Number: Not Available K984590

Device Name: 0.9% Sodium Chloride Flush Syringe

Indication for Use:

The 0.9% Sodium Chloride Flush Syringe is indicated for use in flushing compatible intravenous tubing systems and indwelling intravascular access devices.

Prescription USE ✓
(Per 21 CFR 801.109)

Rebecca Cricenti
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984590

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