K974397

510(k) SUMMARY

FEB 10 1998

Submitted by:

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

Date Prepared:
November 17, 1997

Proposed Device:
Sterile Saline for Catheter Care

Predicate Device:
Current Baxter Respiratory Therapy Solutions

Proposed Device Description:

Baxter Healthcare Corporation intends to manufacture and market Sterile Saline for Catheter Care in 250 mL containers.

Indication for Use:

Sterile Saline for Catheter Care is intended for use in flushing urinary drainage and suction catheters.

Summary of Technological Characteristics of New Device to Predicate Devices

The proposed Sterile Saline for Catheter Care is the same as existing Baxter Respiratory Therapy Solutions, except for the labeling. The solution of normal saline and the container-closure system are the same as those used in the existing Baxter Respiratory Therapy Solutions.

Discussion of Nonclinical Tests; Conclusions Drawn from Nonclinical Tests

The subject of this submission is a change in the indication for a previously cleared medical device. There are no new issues of safety or effectiveness.

NOV 17 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 1998

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

Re: K974397
Trade Name: Sterile Saline for Catheter Care
Regulatory Class: II
Product Code: JOL
Dated: November 17, 1997
Received: November 21, 1997

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 current Good Manufacturing Practice requirement, 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) 594-4618. 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" (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 K974397

Device Name: Baxter Sterile Saline for Catheter Care

Indication For Use:

Baxter Sterile Saline for Catheter Care is indicated for flushing or cleaning urinary drainage and suction catheters.

Rebecca Cucenita
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974397

Prescription Use ✓
(Per 21 CFR 801.109

NOV 17 1997

44