K051370

AUG 1 2 2005

510(k) SUMMARY

Submitted by:

Nanette Hedden
Project Manager, Global Regulatory Affairs
Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, IL 60085

Date Prepared:
May 23, 2005

Proposed Device:
Sterile Water for Device Care
Sterile Saline for Device Care

Predicate Device:
Baxter Sterile Saline for Catheter Care, Welcon Sterile Water for Device Irrigation.

Proposed Device Description:

Sterile Water for Device Care and Sterile Saline for Device Care in 250 mL plastic containers for single use.

Indication for Use:

Baxter Sterile Water for Device Care and Sterile Saline for Device Care are indicated for irrigation and flushing of medical devices.

Summary of Technological Characteristics of New Device to Predicate Devices

The proposed Sterile Saline for Device Care is the same as the existing Baxter Sterile Saline for Catheter Care. Only the name is changed. The Sterile Water for Device Care is the same as Sterile Saline for Catheter Care except for the solution, which is sterile water instead of saline. The container-closure system, plastic materials, and sterilization are the same as those used in marketed Baxter Sterile Saline for Catheter Care products.

Discussion of Nonclinical Tests; Conclusions Drawn from Nonclinical Tests

The subjects of this submission are a name change for a previously cleared medical device and the addition of Sterile Water for Device Care to the product line. There are no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 2005

Ms. Nanette Hedden
Project Manager, Global Regulatory Affairs
Baxter Healthcare Corporation
1620 Waukegan Road, MPGR-AL
McGaw Park, Illinois 60085

Re: K051370
Trade/Device Name: Sterile Saline for Device Care, Sterile Water for Device Care
Regulation Number: 21 CFR 880.6740
Regulation Name: Catheter And Tip Suction
Regulatory Class: II
Product Code: JOL
Dated: May 24, 2005
Received: May 26, 2005

Dear Ms. Hedden:

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 (240) 276-0115. 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/industry/support/index.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

510(k) Number (if known): K051370

Device Name: Sterile Water for Device Care, Sterile Saline for Device Care

Indications For Use: Baxter Sterile Water for Device Care and Sterile Saline for Device Care are indicated for irrigation and flushing of medical devices.

Baxter Sterile Water for Device Care and Sterile Saline for Device Care are not indicated for intravascular injection.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K051370