AUG 14 1998

510(k) Summary

Solution Adminstration Set

Submitted by:

Mary Ellen Snyder
Manager, Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Rt. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:

May 20, 1998

Proposed Device:

Solution Administration Set

Predicate Device:

Nitroglycerin Set
Solution Administration Sets with 0.22 Micron Filter

Proposed Device Description:

The proposed solution set will be used for the administration of intravenous solutions containing the chemotherapeutic drug paclitaxel. The package insert for paclitaxel recommends that the drug be administered parenterally through a polyethylene-lined set because of the concern with diethyl-2-hexylphthalate (DEHP) leaching from DEHP plasticized polyvinyl chloride (PVC). The proposed set is designed to meet the package insert recommendations in that it contains polyethylene-lined tubing, an in-line 0.22 μm filter, and no DEHP plasticized PVC in contact with the solution.

Statement of Intended Use

The solution adminstration set will be used to administer fluids to a patient's vascular system from a container through a needle or catheter inserted into a vein. The proposed solution set will be primarily used to administer solutions containing the chemotherapeutic drug paclitaxel, but can also be used for general solution administration.

Summary of Technological Characteristics of New Device to Predicate Devices

The product is similar to the currently marketed Baxter nitroglycerin set, cleared under K832284A on December 29, 1983. The principal differences between the proposed solution set and the predicate nitroglycerin set include a modified spike design, addition of a 0.22 μm filter, and use of TEHTM to plasticize the PVC components. There are no new materials involved in the proposed device. All solution contact materials to be used in the proposed set are identical to materials used in legally marketed devices under comparable conditions of use.

Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature

Data regarding the functional performance of the proposed solution administration set including its compatibility with paclitaxel have been generated. A description of the functional testing along with test results has been provided. All data indicate that the proposed paclitaxel device meets or exceeds all functional requirements and thus support its suitability for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 1998

Ms. Mary Ellen Synder
Regulatory Affairs Manager
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, Illinois 60073

Re: K981792
Trade Name: Solution Administration Set
Regulatory Class: II
Product Code: FPA
Dated: May 20, 1998
Received: May 21, 1998

Dear Ms. Synder:

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,

S. Dutman for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: Not Available

Device Name: Solution Administration Set

Indication for Use: The solution adminstration set will be used to administer fluids to a patient's vascular system from a container through a needle or catheter inserted into a vein. The proposed solution set will be primarily used to administer solutions containing the chemotherapeutic drug paclitaxel, but can also be used for general solution administration with Baxter Flo-Gard® (6200 and 6300 series) and Colleague™ volumetric infusion pumps.

(Division Sign-Off) B. Butler
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981792