2/19/99

K984381

510(k) SUMMARY

Modified Buretrol® Solution Sets

Submitted by:
Judy Kannenberg
Baxter Healthcare Corporation
I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:
December 7, 1998

Proposed Device:
Modified Buretrol® Solution Sets

Predicate Devices:
Buretrol® Solution Sets

Proposed Device Description:

Baxter markets a line of Buretrol® solution sets which are intended for the administration of infusion fluids from a container to the patient's vascular system. The sets contain a burette chamber which can be used to mix supplementary medication in a measured amount of diluent from the main container. The sets can be adjusted for either metered volume solution administration (intermittent) or continuous solution administration. During intermittent infusion, the main container is shut off above the burette chamber allowing metered (controlled) delivery of the measured volume in the chamber. Some of the Buretrol® sets contain a valve feature which automatically blocks flow after solution has emptied from the burette chamber. The set can be easily converted from the intermittent to the continuous administration mode by closing the air control lever at the top of the burette chamber and allowing continuous infusion from the main container.

The subject of this submission is a change in the material composition of the burette chamber housing. The material of the housing will change from cellulose to polyester. This change is being made to reduce product cost.

DEC 07 1998

Statement of Intended Use:

The Buretrol® Solution Sets with the proposed burette chamber will have the same intended use as sets with the current design of this component. The intended use of these solution administration sets is the administration of fluids from a container into the patient's vascular system through a vascular access device.

Summary of Technological Characteristics of New Device to Predicate Devices

The Buretrol® Solution Sets with the proposed burette chamber are the same as currently marketed sets, except for the material change in the burette chamber housing. The material of the housing will change from cellulose to polyester. All other aspects of the burette chamber will remain unchanged

Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature

The biological and chemical reactivity of the new polyester materials have been assessed using biological methods specified in ISO Standard 10993-1 and USP Physicochemical tests. The materials were found to be acceptable for their intended use.

Data regarding the functional performance of the proposed burette chamber have been generated. The data indicate that the proposed burette chamber meets or exceeds all functional requirements and support its suitability for use in Buretrol® Solution Sets.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1999

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

Re: K984381
Trade Name: Modified Buretrol® Solution Sets
Regulatory Class: II
Product Code: FPA
Dated: December 7, 1998
Received: December 8, 1998

Dear Ms. Kannenberg:

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

K984381

510(k) Number: Not Available

Device Name: Modified Buretrol® Solution Sets

Indication for Use:

The Buretrol® Solution Sets with the proposed burette chamber will have the same intended use as sets with the current design of this component. The intended use of these solution administration sets is the administration of fluids from a container into the patient's vascular system through a vascular access device.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984381

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