K9931

NOV 17 1999

510(k) SUMMARY

Modified Blood Administration Sets

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

Date Prepared:
September 17, 1999

Proposed Device:
Modified Blood Administration Sets

Predicate Devices:
Blood /Solution Sets

Proposed Device Description:

Baxter currently markets a line of intravascular administration sets containing 80 micron and 170 to 260 micron blood filters. These sets are used in blood transfusion procedures for the administration of blood, blood components and solutions. We plan to replace the current 80 micron and 170 to 260 micron filters in these blood sets with a modified filter design. The key differences between the current and proposed blood filters are in the material composition and design of the filter chamber. The current filters are polyester and nylon screen type filters housed in PVC chambers. The new filters will be polyester screen type filters but will be housed in chambers of a different material and design. The mesh size of the polyester screen filter will be standardized to 200 microns to meet ISO standard ISO 1135-4.

Statement of Intended Use:

The modified Baxter blood sets have the same intended use as currently marketed Baxter blood sets. The intended use of these sets is the administration of blood, blood components or solutions from a container into the patient's vascular system through a vascular access device.

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Summary of Technological Characteristics of New Device to Predicate Devices

The proposed Baxter sets are identical to currently marketed Baxter sets except for the design and material changes in the blood filters. All other technological characteristics in the blood administration sets remain unchanged.

Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature

The biological and chemical reactivity of the new 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 blood filters have been generated. The data indicate that the proposed blood filters meet or exceed all functional requirements and support their suitability for use in blood administration sets.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 1999

Ms. Judy Kannenberg
Manager, Regulatory Affairs
Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Re: K993120
Trade Name: Modified Blood Administration Sets
Regulatory Class: II
Product Code: BRZ
Dated: September 17, 1999
Received: September 20, 1999

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 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

K993120

510(k) Premarket Notification
Modified Blood Administration Sets

510(k) Number: Not Available

Device Name: Modified Blood Administration Set

Indication for Use:

The modified Baxter blood sets have the same intended use as currently marketed Baxter blood sets. The intended use of these sets is the administration of blood, blood components or solutions from a container into the patient's vascular system through a vascular access device.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993120

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