K992894

NOV 24 1999

Renal Division

Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, Il 60085-6730

847-473-6030

BAXTER

510(k) SUMMARY
BAXTER MERIDIAN HEMODIALYSIS MACHINE

Submitter's name, addresss, phone, fax, contact person	Baxter Healthcare Corporation Renal Division 1620 Waukegan Road McGaw Park, IL 60085 Phone: (847) 473-6335 Fax: (847) 473-6952 Contact: Robert Wilkinson
Date prepared	July 28, 1999
Trade name of device	Baxter Meridian Hemodialysis Machine
Common name	Hemodialysis Machine
Classification name	High Permeability Hemodialysis System (per 21CFR 867.5860)
Substantially equivalent devices	Baxter 1550 Hemodialysis Machine and the 1550, Single Needle Patient System [510(k) number K883111 and K922757, respectively]
Description of the device	The Baxter Meridian is a single patient hemodialysis instrument that prepares dialysis solution, circulates blood through an extracorporeal circuit of blood tubing and hemodialyzer, and monitors the system for safe operating conditions. Its features include high blood flow rates, automatic ultrafiltration control, variable sodium and bicarbonate dialysis capabilities, and patient prescription entry through a patient data card. Optional features include automated patient blood pressure monitoring, a heparin pump and a sodium administration button.
Intended use of the device	The Baxter Meridian Hemodialysis machine is part of a high permeability hemodialysis system which consists of a controlled dialysate delivery system that incorporates an ultrafiltration controller to prevent excessive loss of water from the patient's blood, an extracorporeal blood set and a high permeability dialyzer. The standard features of the Meridian machine include high blood flow rate capacity (for shortened hemodialysis treatment time), automatic ultrafiltration, standard and variable bicarbonate and sodium capabilities and automated chemical disinfection. The Meridian machine will operate in either the bicarbonate or acetate mode for concentrates. The Meridian machine is designed to operate in the chronic and acute dialysis environment.
Comparison of technological characteristics between new and predicate devices	The Baxter Meridian Hemodialysis Machine consists of a Baxter 1550's hydraulic (fluid) components repackaged in a new structural foam cabinet with a CRT user interface and repackaged electronics.

2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1999

Mr. Robert Wilkinson, RAC
Director, Regulatory Affairs
Renal Division
Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, Illinois 60085

Re: K992894
Meridian Hemodialysis Machine, Model 5M5576
Dated: August 24, 1999
Received: August 27, 1999
Regulatory class: III
21 CFR §876.5860/Product code: 78 KDI

Dear Mr. Wilkinson:

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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):K992894

Device Name: **Baxter Meridian Hemodialysis Machine (Model 5M5576)**

Indications For Use:

The Baxter Meridian machine is part of a high permeability hemodialysis system which consists of a controlled dialysate delivery system that incorporates an ultrafiltration controller to prevent excessive loss of water from the patient's blood, an extracorporeal blood set and a high permeability dialyzer. The standard features of the Meridian machine include high blood flow rate capacity (for shortened hemodialysis treatment time), automatic ultrafiltration control, standard and variable bicarbonate and sodium capabilities and automated chemical disinfection. The Meridian machine will operate in either the bicarbonate or acetate mode for concentrates.

The Meridian Hemodialysis Machine is designed to operate in the chronic and acute dialysis environment.

(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_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT and Radiological Devices
510(k) Number K992894

3