510(k) SUMMARY
BAXTER MERIDIAN HEMODIALYSIS MACHINE

Submitter's name, addresss, phone, fax, contact person	David E. Curtin Baxter Healthcare Corporation Renal Division 1620 Waukegan Road McGaw Park, IL 60085 (847) 473-6079 (847) 473-6952 (FAX)
Date prepared	
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 Meridian Hemodialysis Machine - K992894
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 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 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 is technologically the same as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 24 2006

David E. Curtin, R.A.C.
Associate Director, Regulatory Affairs
Baxter Healthcare Corporation
Renal Division, MPGR-A2E
1620 Waukegan Road
MCGAW PARK IL 60085

Re: K053539
Trade/Device Name: Meridian Hemodialysis Machine
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: April 25, 2006
Received: April 27, 2006

Dear Mr. Curtin:

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 (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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K053539

Device Name: Meridian Hemodialysis Machine

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 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 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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053539