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K021615

510(K) SUMMARY

Submitter's Name:	David E. Curtin, RAC
Address:	1620 Waukegan Rd. MPGR-A2E
Phone:	(847) 473-6079
Fax:	(847) 473-6952
Contact:	David E. Curtin
Date Prepared:	5/14/02
Trade Name:	Baxter Accura System Therapy
Common Name:	Blood Pumping, Ultrafiltration Control and Fluid Replacement System for Continuous Renal Replacement Therapy
Classification Name:	High Permeability Hemodialysis System per 21 CFR 876.5860
Equivalent Predicate:	PRISMA™ System (K993064, K981681, K946279) Diapact CRRT (K973322) Bm11 Blood Monitor Pump Disposable Tubing Set (K911315/A)
Device Description:	The Accura System hardware consists of blood pumps, scales and various monitoring detectors and alarms designed for Continuous Renal Replacement Therapy (CRRT) and Therapeutic Plasma Exchange Therapy. This device was developed to provide pump assisted Slow Continuous Ultrafiltration (SCUF), Continuous Veno-Venous Hemofiltration (CVVH), Continuous Veno-Venous Hemodialysis (CVVHD) and Continuous Veno-Venous Hemodiafiltration (CVVHDF); four modalities used for treating acute renal failure and/or fluid overload. Additionally, the Accura System was developed to provide the pump assisted Therapeutic Plasma Exchange (TPE) therapy.
Intended Use:	The Baxter Accura System is indicated for continuous solute and/or fluid removal in patients with acute renal failure or fluid overload. The Baxter Accura System may also be used in Therapeutic Plasma Exchange (TPE) therapies.

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Summary of the Technological Characteristics Compared to the	The general design and material of the Baxter Accura System is similar to the PRISMA™ CFM System currently marketed by Gambro Renal Care Products, and cleared under K993064, K981681 and K946279 and to the Diapact CRRT machine marketed by B. Braun Medical and cleared under K973322.
Predicate Device:	The technological characteristics displayed by the subject Baxter Accura System are similar to the predicate devices and do not raise any new types of safety and effectiveness issues, when compared to the PRISMA™ CFM System or Diapact CRRT.
Clinical Data:	N/A
Conclusions Drawn from Tests:	All functions of the Baxter Accura System were tested and validated according to design specifications. Based on the validation results, all functions meet their respective required specifications. Additionally, components of the disposable tubing set have met the biological requirements of ISO 10993-1: Biological Evaluation of Medical devices – Part: Guidance on selection of tests. The validation of the sterilization cycle for the Baxter Accura System disposable tubing set is based upon the ANSI/AAMI/ISO 11135:1994 "Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization". Additionally, the Baxter Accura™ System meets the following applicable IEC 60601 general and particular standards: IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, and IEC 60601-2-16.
Additional Information Requested by FDA:	None to date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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David E. Curtin, RAC
Associate Director,
Regulatory Affairs
Renal Division
Baxter Healthcare Corporation
1620 Waukegan Road
MCGAW PARK IL 60085-6730

Re: K021615
Trade/Device Name: Baxter Accura System, Model 5M5660
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: August 19, 2002
Received: August 20, 2002

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 (PMA), it may be subject to 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.

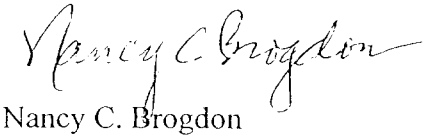
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,



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): K021615

Device Name: **Baxter Accura System for Continuous Renal Replacement Therapy**

Indications For Use:

The Baxter Accura System is indicated for continuous solute and/or fluid removal in patients with acute renal failure or fluid overload. The Baxter Accura System may also be used in Therapeutic Plasma Exchange (TPE) therapies.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lazzara

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021615

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)