K970591

SEP - 9 1997

510(K) SUMMARY

Submitter's name:	Ann Marie Pahlman
Address:	1620 Waukegan Rd. MPRA-2E McGaw Park, IL 60080
Phone:	847 473 6078
Fax:	847 473 6952
Contact:	Robert Wilkinson or Ann Marie Pahlman
Date Prepared:	May 20, 1997
Trade name:	bm11a Blood Monitor Pump for Continuous Renal Replacement
Common name:	Blood Monitor Pump for Continuous Renal Replacement
Classification name:	High Permeability Hemodialysis System per 21 CFR 876.5860
Equivalent predicate:	bm11 Blood Monitor Pump (K911315/A)
Device Description:	The bm11a Blood Monitor Pump is designed for use in the following extracorporeal therapies: - Continuous Venovenous Hemofiltration (CVVH) - Continuous Venovenous Hemodiafiltration (CVVHD) - Slow Continuous Ultrafiltration (SCUF)
Intended Use:	The bm11a Blood Monitor Pump is designed for continuous renal replacement therapy in patients with acute renal failure, as prescribed by a physician.
Summary of the technological characteristics compared to the predicate device	The general design and materials of the subject Blood Monitor Pump is the same as the currently marketed BM11 Blood Monitor Pump. The structure of the software modules was set up to distinguish between Master and Controller system errors. The characteristics displayed by the subject bm11a Blood Monitor Pump do not raise any new types of safety and effectiveness issues, when compared to the currently marketed bm11 Blood Monitor Pump. The bm11a Blood Monitor Pump was designed to UL2601 - General electrical safety of medical equipment. A fault tree, hazard analysis, EMC testing, and software System integration validation were conducted on the bm11a Blood Monitor Pump.

Clinical data: N/A

Conclusions drawn from tests: All functions of the bm11a Blood Monitor Pump were tested and validated according to design specifications. Based on the validation results, all functions meet their respective required specifications.

Additional information requested by FDA: none to date

Official Correspondent:

Robert L. Wilkinson
Director, Regulatory Affairs
Renal Division

Prepared by:

Ann Marie Pahlman
Manager Regulatory Affairs
Renal Division

5/20/97
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 1997

Ms. Ann Marie Pahlman
Manager Regulatory Affairs
Renal Division
Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, Illinois 60085-6730

Re: K970591
bm11a Blood Monitor Pump
Dated: May 20, 1997
Received: May 21, 1997
Regulatory class: III
21 CFR §876.5860/Product code: 78 KDI

Dear Ms. Pahlman:

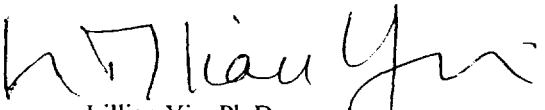
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Current Good Manufacturing Practice requirement, 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/dsmamain.html".

Sincerely yours,



Lillian Yin, Ph.D.
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): K970591

Device Name: bm11a Blood Monitor Pump

Indications for Use: The bm11a Blood Monitor Pump is designed for continuous renal replacement therapy in patients with acute renal failure, as prescribed by a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Rathmell

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K970591

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

(Optional Format 1-2-96)