510(K) SUMMARY

NOV 12 1997

Submitter's name: Ann Marie Pahlman MPR A-2E
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Contact: Ann Marie Pahlman or Robert Wilkinson
Date Prepared: February 20, 1997

Trade name: CA® Cellulose Acetate Hollow Fiber Dialyzer
Common name: Hemodialyzer
Classification name: Hemodialysis System and Accessories per 21 CFR 876.5820

Equivalent predicate: CA® Cellulose Acetate Hollow Fiber Dialyzers

Device Description: Models CA-90, CA-110, CA-130, and CA-150 Hemodialyzers

Intended Use: Intended specifically for use in patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It may also be indicated in the treatment of patients intoxicated with poisons or drugs.

Summary of the technological predicate device: The general function and materials of the subject CA® Hemodialyzers are identical to the Baxter predicate Dialyzers.

Clinical data: Clinical data was collected according to the FDA Guidance for Hemodialyzer Reuse Labeling.

Conclusions drawn All patient contact components of the subject CA® Hemodialyer have previously met the biological requirements of the guidelines for safety screening of materials for USP XXI Class VI materials. These Dialyzers are sterilized by the Nissho corporation using Ethylene Oxide Gas (EtO) to a sterility asurance level (SAL) of 1×10^{-6}. The validation of the sterilization cycle for the CA® Hemodialyzer is based upon the Association for the Advancement of Medical Instrumentation (AAMI) Guideline (ST-27-Industrial Ethylene Oxide (EtO) Sterilization of Medical Devices). Prior to release, sterilant residues of EtO, ECH and EG are consistent with the proposed limits for the "blood ex vivo" device category as published in the June 23, 1978 Federal Register.

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Pyrogen testing meets the requirements of JMHW Notification No. 494, "Approval Requirements for Dialyzers" and the Japanese Pharmacopeia "Pyrogen test."

Particles are compared to USP 23 <788> limits for Large Volume Injections (LVI) solutions and ASTM F25-68.

Functional testing for blood side integrity and conformance to manufacturing specifications are performed as in-process and/or final inspections prior to product release ensuring a quality product.

In Vivo and In Vitro performance data, and directions for reuse have been included in the labeling.

Additional information requested by FDA: none to date

Official Correspondent:

Robert L. Wilkinson

Robert L. Wilkinson
Director Regulatory Affairs

2/20/97
Date

Prepared by:

Ann Marie Pahlman

Ann Marie Pahlman
Manager Regulatory Affairs

2/20/97
Date

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 1997

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

Re: K970661
Multiple Use Labeling for CA® Cellulose Acetate
Hollow Fiber Dialyzers - Models 90, 110, 130, and 150
Dated: August 11, 1997
Received: August 14, 1997
Regulatory class: II
21 CFR §876.5820/Product code: 78 MSE

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,

William Yin

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): K970661

Device Name: CA Cellulose Acetate Hollow Fiber Dialyzers

Indications for Use:

Hemodialysis with these dialyzers is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It may also be indicated in the treatment of patients intoxicated with poisons or drugs. This dialyzer is indicated for single use or reuse. If the dialyzer is reused on the same patient, the reuse procedure and disinfectant specified in the Direction Insert must be followed. No other reuse procedure or disinfectant has been evaluated for clinical acceptability.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Nathan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K970661

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