K963933

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510(K) SUMMARY

Submitter's name:	Ann Marie Pahlman MPR A-2E
Address:	1620 Waukegan Rd. McGaw Park, IL 60080
Phone:	847 473-6078
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Contact:	Ann Marie Pahlman or Robert Wilkinson
Date Prepared:	September 20, 1996
Trade name:	Polysynthane (PSN) Hemodialyzer
Common name:	Hemodialyzer
Classification name:	Hemodialysis System and Accessories per 21 CFR 876.5820
Equivalent predicate:	CF Capillary Flow Dialyzers, CA Cellulose Acetate Hollow Fiber Dialyzers, HT Hollow Fiber Dialyzers
Device Description:	Model PSN-120 PSN Hemodialyzer Model PSN-140 PSN Hemodialyzer
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 PSN Hemodialyzers are the same as the Baxter predicate Dialyzers. Differences in the subject PSN Hemodialyzers to the predicate Baxter Dialyzers consist of a change in the fiber bundle material and a slight change in clearance values for urea, creatinine and Vitamin B 12.
Clinical data:	N/A
Conclusions drawn from tests:	Components of the subject PSN Hemodialyzers, with the exception of the fiber bundle, have previously met the biological requirements of the guidelines for safety screening of materials for USP XXI Class VI materials. The fiber bundle was tested as suggested by to ISO 10993-1: Biological Evaluation of Medical Devices - Part 1. guidelines. The validation of the sterilization cycle for the PSN Hemodialyzer is based upon the Association for the Advancement of Medical Instrumentation (AAMI) Guideline (ST-27-Industrial Ethylene Oxide (EO) Sterilization of Medical Devices) to ensure a sterility assurance level (SAL) of $1x10^{-6}$. Prior to release, sterilant residues of EO, 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 of the subject bloodlines meets the requirements of Chapter 161, Transfusion and Infusion Assemblies and Similar Medical Devices of Supplement 2 of the USP.

Particles are compared to USP 23 limits for Large Volume Injections (LVI) solutions.

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.

Additional information requested by FDA: none to date

Official Correspondent:

Robert L. Wilkinson

Robert L. Wilkinson
Director Regulatory Affairs

9/23/96
Date

Prepared by:

Ann Marie Pahlman

Ann Marie Pahlman
Manager Regulatory Affairs

9/23/96
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K963933
PNS Hollow Fiber Dialyzer - Models 120 and 140
Dated: October 21, 1997
Received: October 23, 1997
Regulatory class: II
21 CFR §876.5820/Product code: 78 FJI

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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): _____

Device Name: PSN Hollow Fiber Dialyzer

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D Tathwell

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K9

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

(Optional Format 1-2-96)