

MAY 19 1998

K980658

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:** February 16, 1998

**Trade name:** Polysynthane (PSN™) Hemodialyzer  
**Common name:** Hemodialyzer  
**Classification name:** Hemodialysis System and Accessories per 21 CFR 876.5820

**Equivalent predicate:** CA® Hollow Fiber Dialyzers,  
PSN™ Polysynthane Dialyzers

**Device Description:** Model PSN-130 Hemodialyzer  
Model PSN-150 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 Dialyzers.** The general function and materials of the subject PSN™ Hemodialyzers are the same as the Baxter predicate Dialyzers with a slight change in clearance values for urea, creatinine, Vitamin B 12, and ultrafiltration similar to that of the CA® Hollow Fiber Dialyzers.

**Clinical data:** N/A

**Conclusions drawn** Components of the subject PSN™ Hemodialyzers have met the biological requirements of ISO 10993-1: Biological Evaluation of Medical Devices - Part 1: Guidance on selection of tests. 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  $1 \times 10^{-6}$ . 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.

**510(K) SUMMARY**

**February 16, 1998**

**Polysynthane (PSN™) Hemodialyzer**

**Page 2 of 2**

Pyrogen testing of the subject dialyzers meets the requirements of Chapter 161, Transfusion and Infusion Assemblies and Similar Medical Devices of Supplement 2 of the USP.

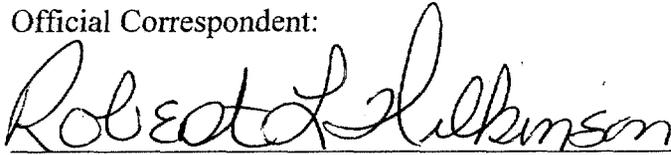
Particles are counted per USP XXIII <788>.

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

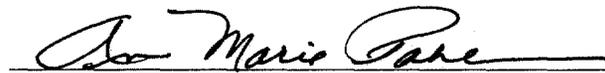
Official Correspondent:

  
\_\_\_\_\_

Robert L. Wilkinson  
Director Regulatory Affairs

2/16/98  
Date

Prepared by:

  
\_\_\_\_\_

Ann Marie Pahlman  
Manager Regulatory Affairs

2/16/98  
Date

MAY 19 1998

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

Re: K980658  
PSN® Polysynthane Hemodialyzers  
Models 130 and 150  
Dated: February 16, 1998  
Received: February 19, 1998  
Regulatory Class: II  
21 CFR 876.5820/Procode: 78 FJI

Dear Ms. Pahlman:

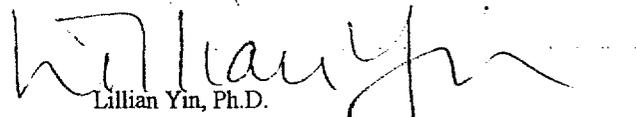
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirements, 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/dsma/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): \_\_\_\_\_

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)

Dobler R. Sathling /  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K980658

Prescription Use    
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)