

12/7/99

K990643

**510(k) SUMMARY
OF SAFETY AND EFFECTIVENESS**
[As Required by 21 CFR 807.92(c)]

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92(a).

I. SUBMITTER INFORMATION

- a. Company Name: Althin Medical, Inc.
- b. Company Address: 14620 NW 60th Avenue
Miami Lakes, Florida 33014-9308
- c. Company Phone: (305) 823-5240
- d. Contact Person: Amaury Sanchez
Senior Regulatory Compliance
Coordinator
- e. Date Summary Prepared: February 24, 1999

II. DEVICE IDENTIFICATION

- a. Trade/Proprietary Name: PS 15® Hemodialyzer
- b. Common Name: Hemodialyzer
- c. Classification Name: High Permeability Hemodialyzer 21 CFR
876.5860

III. Substantially Equivalent Legally Marketed Device:

Company	Device	510(k) No.	Date Cleared
Althin Medical, Inc.	Altrex 170 Hemodialyzer	K945597	3/8/95
Fresenius Medical Care	Fresenius F60 Polysulfone Dialyzer	K852251	7/25/85

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The PS 15® Hemodialyzer is substantially equivalent to other predicate devices currently in commercial distribution in terms of their intended use. The fundamental technical characteristics are similar to those of the predicate devices.

IV. DEVICE DESCRIPTION

The PS 15® Hemodialyzer consists of approximately 13,000 polysulfone hollow fibers encapsulated in polyurethane resin with an outer housing and headers made of Polycarbonate. The device is packaged in a blister package composed of Glycol modified Polyethylene Terephthalate for the bottom web, and a foil laminate for the top web.

The PS 15® Hemodialyzer has two compartments, the blood compartment and the dialysate compartment, separated by the polysulfone permeable membrane. Blood flows from the patient access site through the tubing of the extracorporeal system and accessories to the blood compartment of the dialyzer. From the blood compartment, undesirable substances in the blood pass through the membrane into the dialysate compartment of the dialyzer. Circulation and monitoring of dialysate flow through the dialysate compartment is controlled by the dialysate delivery system, while the ultrafiltration controller prevents excessive loss of water from the patient's blood.

V. INTENDED USE OF THE DEVICE

The disposable PS 15® Hemodialyzer is Intended for use in conjunction with commercially available blood tubing, blood access devices and related hemodialysis equipment. The intended use of the PS 15® Hemodialyzer and predicate Altrex 170 Hemodialyzer is identical in that the devices are intended for hemodialysis in patients with acute or chronic renal failure, when conservative therapy is judged to be inadequate. Both devices are labeled as sterile, non-pyrogenic, and for single use only. The devices are restricted to sale by or on the order of a physician.

VI. COMPARISON OF TECHNICAL CHARACTERISTICS

The design configuration of the PS 15® Hemodialyzer is similar to legally marketed devices from Althin Medical, Inc. and polysulfone membrane from Fresenius Medical Care.

With the exception of polysulfone, the PS 15® Hemodialyzer and predicate Altrex 170 use identical materials, similar manufacturing processes, the same package and are gamma sterilized.

The polysulfone membrane used in the PS 15® Hemodialyzer is substantially equivalent to other polysulfone membranes marketed by Fresenius Medical Care. Results from the functional, chemical and biological tests demonstrate that the PS 15® Hemodialyzer is equivalent to a legally marketed device.

A comparison of the features of the PS 15® Hemodialyzer and those of the previously cleared predicate device are presented in the following table.

Feature	PS 15® Hemodialyzer	Altrex 170 Hemodialyzer
Classification Name	High Permeability Hemodialyzer or artificial kidney	High Permeability Hemodialyzer or artificial kidney
Classification	Class III device per 21 CFR 876.5860(b)	Class III device per 21 CFR 876.5860(b)
Panel	Gastroenterology and Urology	Gastroenterology and Urology
Product Code	78KDI	78KDI
Indications for Use	Same	Same
Product Specifications	Similar	Similar
Component configuration	Same	Same
Component functions	Same	Same
Compatible Hemodialysis Equipment	Same	Same
Labeling	Similar content	Similar content
Intended use	Same	Same
Labeled sterile, non-pyrogenic for single use only	Yes	Yes
Restricted to sale by or on Order of a Physician	Yes	Yes
Materials	Polysulfone Polycarbonate Polyurethane ABS Polyethylene	Cellulose Acetate Polycarbonate Polyurethane ABS Polyethylene
Design	Similar	Similar
Hemolysis	< 3% of Control	< 3% of Control
Pyrogenicity	Non-pyrogenic	Non-pyrogenic
Acute Toxicity	Meets USP	Meets USP
Sterility	Sterile	Sterile
Leakage	No Leaks	No Leaks
Sterilization Method	Gamma	Gamma
Packaging	Foil/PETG tray	Foil/PETG tray

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VII. FUNCTIONAL TESTING

Functional testing has been conducted to evaluate the performance of the PS 15® Hemodialyzer. The results of the functional testing attest that the PS 15® Hemodialyzer conforms to its specifications and has demonstrated the suitability of the PS 15® Hemodialyzer for its intended use.

	PS 15® Hemodialyzer	**Altrex 170	**Fresenius F60
Total Blood Volume Measured (ml)	79	91	83
Effective Membrane Surface Area (m ²)	1.5	1.61	1.25
Wall Thickness (μ)	20	30	40
Maximum TMP	500	500	650
Clearance (ml/min)*			
Urea	171	178	185
Creatinine	155	163	172
Phosphate	141	155	170
B ₁₂	73	106	118

*Q_b 200, Q_d 500 *in vitro* Q_r 10 ml/min UFR

***In Vitro* Q_r 0.0 ml/min

The Althin Medical, Inc., PS 15® Hemodialyzer is similar in design, construction, indication for use, and performance characteristics to other commercially available hemodialyzers. The results from nonclinical tests demonstrate that the PS 15® Hemodialyzer is substantially equivalent to predicate devices.

VIII. BIOCOMPATIBILITY TESTING

All appropriate biocompatibility tests have been performed. The following tests were performed:

Test Name	Results
Cytotoxicity Study (USP Elution Method)	Pass
ISO Sensitization Study in the Guinea Pig (Maximization Method)	Pass
Subchronic Intravenous Toxicity Study in the Rat	Pass
Acute Intracutaneous Reactivity Study in the Rabbit	Pass
Acute Systemic Toxicity Study in the Mouse	Pass
ISO Muscle Implantation Study in the Rabbit	Pass
Genotoxicity: Salmonella typhimurium Reverse Mutation Study	Pass
Genotoxicity: Sister Chromatid Exchange Study	Pass
Genotoxicity: Chromosomal Aberration Study in Mammalian Cells	Pass
Rabbit Pyrogen Study	Pass
Hemolysis Study <i>In Vitro</i> Procedure	Pass
Microtoxicity and Hemolysis Test	Pass

The results of the biocompatibility testing demonstrate that the PS 15® Hemodialyzer conforms to the specifications set forth. The subject and legally marketed devices conform to similar specifications.

IX. Conclusions

The information included in this notification demonstrate that the PS 15® Hemodialyzer and predicate device are similar in design, materials, manufacturing processes, performance, safety, effectiveness, intended uses, indications, labeling and instructions for use. Therefore, based on the information provided in this premarket notification, the PS 15® Hemodialyzer is considered substantially equivalent to the predicate devices.



DEC - 7 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Amaury Sanchez, RAC
Senior Regulatory Compliance Coordinator
Althin Medical, Inc.
14620 N.W. 60th Avenue
Miami Lakes, FL 33014

Re: K990643
PS 15[®] Polysulfone Hemodialyzer
Dated: June 24, 1999
Received: June 28, 1999
Regulatory Class: III
21 CFR §876.5860/Procode: 78 KDI

Dear Mr. Sanchez:

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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

K990643

Device Name:

PS 15® Polysulfone Hollow Fiber Membrane Hemodialyzer

Indications for Use:

The PS 15® Hemodialyzer is intended for hemodialysis in patients with acute or chronic renal failure, when conservative therapy is judged to be inadequate.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR Over-The-Counter Use

Colin M. Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number

K990643