MAY 3 0 2003

K031378

Fresenius Medical Care

Fresenius Ultraflux Single Use Hemodialyzer "Special" 510(k) Premarket Notification

Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Name:	Fresenius Medical Care North America
Address:	95 Hayden Ave Lexington, MA 02420
Phone:	1-781-402-9068
Fax:	(781) 402-9635
Contact Person:	Arthur Eilinsfeld, Director of Regulatory Affairs
Date of Preparation:	29 April 2003

B. Device Name:

Common Name: Dialyzer, High Permeability with or without Sealed Dialysate System

Product Code/Classification Panel: 78KDI/Gastroenterology-Urology

Classification: Class II per §876.5860

C. Predicate Device

The predicate devices for the Fresenius Ultraflux Hemodialyzers are:

- Fresenius Optiflux 200NR - #K002277 (8/25/00);
- Gambro Polyflux 17S - #K982414 (3/26/99).

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Summary of Safety and Effectiveness

D. Indications for Use:

The Fresenius Ultraflux dialyzer is designed for single use acute and chronic hemodialysis.

E. Substantial Equivalence:

1. Is the product a device?

YES - The Ultraflux dialyzers are devices pursuant to 21 CFR §201 [321] (h).

2. Does the new device have the same intended use?

YES – The intended use for the Ultraflux is identical to that for the Optiflux 200NR and is as follows:

Intended Use for Ultraflux

The Fresenius Ultraflux dialyzer is designed for single use acute and chronic hemodialysis.

Intended Use for Optiflux 200NR

Optiflux 200NR dialyzers are designed for single use acute and chronic hemodialysis.

3. Does the device have technological characteristics that raise new types of safety or effectiveness questions?

NO – The Ultraflux are equivalent in materials, sterilization and indications for use to the currently manufactured Optiflux 200NR. The technological characteristics of the Ultraflux are equivalent to those of the Optiflux 200NR and Gambro Polyflux 17S and raise no new types of safety or effectiveness questions.

4. Does descriptive or performance information demonstrate equivalence?

YES – Fresenius Medical Care North America believes that the information provided in this submission clearly describes the Ultraflux and demonstrates that it is substantially equivalent to the Optiflux 200NR.

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Summary of Safety and Effectiveness

F. Safety Summary

The Ultraflux hemodialyzers are substantially equivalent in construction, design, materials, and intended use to the commercially available Fresenius Optiflux hemodialyzers. In addition, testing of Ultraflux hemodialyzers indicates that the dialyzers are safe and effective for their intended use.

In vitro testing was performed to determine the following: priming volume, blood-side and dialysate-side pressure drops, ultrafiltration coefficient, urea clearance, creatinine clearance, Vitamin B12 clearance, phosphate and lysozyme clearance. No clinical testing was performed.

G. General Safety and Effectiveness Concerns

The device labeling contains a Package Insert, which includes indications for use, cautions and warnings, as well as the general operating instructions required for proper use of the device. This information promotes safe and effective use of the dialyzer.

Arthur Eilinsfeld
Director of Regulatory Affairs

4/29/03
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2003

Ms. Nichole Riek
Regulatory Affairs Supervisor
Fresenius Medical Care North America
Two Ledgemont Center
95 Hayden Avenue
LEXINGTON MA 02173

Re: K031378
Trade/Device Name: Fresenius Ultraflux Single Use Hemodialyzer
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: April 29, 2003
Received: May 1, 2003

Dear Ms. Riek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Fresenius Medical Care

Fresenius Ultraflux Single Use Hemodialyzer
"Special" 510(k) Premarket Notification

Indications for Use Statement

Device Name:

Fresenius Ultraflux Hemodialyzers

Indications for Use:

The Fresenius Ultraflux dialyzer is designed for single use acute and chronic hemodialysis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031378