K04-3244
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DEC 20 2004

Fresenius Medical Care

Fresenius Optiflux F20NR^e, F18NR^e and F16NR^e Single Use Hemodialyzers "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 Two Ledgemont Center Lexington, MA 02420
Phone:	1-781-402-9068
Fax:	(781) 402-9635
Contact Person:	Arthur Eilinsfeld, Director of Regulatory Affairs
Date of Preparation:	19 November, 2004

B. Device Name:

Proprietary Name: Fresenius Optiflux F20NR^e, F18NR^e and F16NR^e Hemodialyzers

Common Name:

- Optiflux F20NR^e *and* Optiflux F18NR^e: Dialyzer, High Permeability with or without Sealed Dialysate System
- Optiflux F16NR^e: Dialyzer, Capillary, Hollow Fiber

Product Code/Classification Panel:

- Optiflux F20NR^e *and* Optiflux F18NR^e: 78KDI/Gastroenterology-Urology
- Optiflux F16NR^e: 78FJI/Gastroenterology-Urology

Classification:

- Optiflux F20NR^e *and* Optiflux F18NR^e: Class II per §876.5860
- Optiflux F16NR^e: Class II per §876.5820

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C. Predicate Devices

The Fresenius Optiflux F20NR^e, F18NR^e, and F16NR^e are modified versions of the Fresenius Optiflux 200NR and Fresenius Hemoflow F7NR^e, which were cleared under the following premarket notifications:

Optiflux 200NR:

- K002277 (8/25/00)

Hemoflow F7NR^e

- #K002761 (12/04/00)

D. Indications for Use/Intended Use

Optiflux F20NR^e, F18NR^e, and F16NR^e dialyzers are designed for single use acute and chronic hemodialysis.

E. Substantial Equivalence:

1. Is the product a device?

YES - The Fresenius Optiflux F20NR^e, F18NR^e, and F16NR^e hemodialyzers 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 Optiflux F20NR^e, F18NR^e, and F16NR^e hemodialyzers is equivalent to that for the Fresenius Optiflux 200NR and is as follows:

Optiflux F20NR^e, F18NR^e, and F16NR^e - Intended Use

Optiflux F20NR^e, F18NR^e, and F16NR^e dialyzers are designed for single use acute and chronic hemodialysis.

Fresenius Optiflux 200NR - Intended Use

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

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

   NO – The Optiflux F20NR^e, F18NR^e, and F16NR^e are e-beam sterilized, low-flux versions of the Optiflux 200NR. The technological characteristics of the Optiflux F20NR^e, F18NR^e, and F16NR^e are equivalent to those of the Optiflux 200NR and Hemoflow F7NR^e 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 Optiflux F20NR^e, F18NR^e, and F16NR^e and demonstrates that they are substantially equivalent to the Fresenius Optiflux 200NR and Hemoflow F7NR^e.

F. Safety Summary

The Optiflux F20NR^e, F18NR^e, and F16NR^e dialyzers are substantially equivalent in construction, design, materials, and intended use to the commercially available Fresenius F7NR^e and Fresenius Optiflux 200NR dialyzers. In addition, testing of the Optiflux F20NR^e, F18NR^e, and F16NR^e indicates that they are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 2004

Ms. Nichole Riek
Regulatory Affairs Supervisor
Fresenius Medical Care North America
95 Hayden Avenue
LEXINGTON MA 02420

Re: K043244
Trade/Device Name: Fresenius Optiflux 20NR^e, 18NR^e and 16NR^e Hemodialyzers
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Product Code: 78 KDI
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Product Code: 78 FJI
Regulatory Class: II
Dated: November 19, 2004
Received: November 23, 2004

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 Section 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:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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

Indications for Use

510(k) Number (if known): K043244

Device Name: Fresenius **Optiflux F20NR^e, F18NR^e, and F16NR^e Hemodialyzers**

Indications For Use:

Optiflux F20NR^e, F18NR^e, and F16NR^e dialyzers are designed for single use acute and chronic hemodialysis.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) ~~AND/OR~~ Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043244