Confidential Fresenius Medical Care

OCT 28 2008

Fresenius Optiflux® F250NR Dialyzer
510(k) Summary

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:	920 Winter Street Waltham, MA 02451-1457
Phone:	1-781-699-4475
Fax:	(781) 699-9635
Contact Person:	Janet C. Kay RAC Regulatory Affairs Manager
Date of Preparation:	January 23, 2007

B. Device Name:

Proprietary Name:	Optiflux® F250NR dialyzer
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 Devices

The Optiflux F250NR dialyzer is substantially equivalent to the Baxter Xenium 210 dialyzer and the Rexeed 25S dialyzer.

Baxter Xenium Dialyzer Model 210

- K062079 (10/19/2006)

Asahi Kasei Rexeed Dialyzer Model 25S

- K051187 (6/8/05)

D. Indications for Use/Intended Use:

The Optiflux F250NR dialyzers are intended for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate.

E. Substantial Equivalence:

5. Is the product a device?

YES - The Fresenius Optiflux F250NR dialyzer is a device pursuant to 21 CFR §201 [321] (h).

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

YES – The intended use for the Fresenius Optiflux F250NR dialyzer is equivalent to the Baxter Xenium dialyzer model 210 and Asahi Rexeed model 25S

Fresenius Optiflux F250NR dialyzer - Intended Use

Optiflux F250NR dialyzers are intended for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate.

Baxter Xenium dialyzer model 210 - Intended Use

Hemodialysis with Xenium dialyzers is indicated for patients with renal failure with conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

Asahi Rexeed dialyzer model 25S – Intended Use

Asahi Rexeed dialyzers are intended for use in hemodialysis treatments in patients who have chronic or acute renal failure.

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

NO – The technological characteristics of the Fresenius Optiflux F250NR dialyzer is equivalent to that of the Baxter Xenium model 210 dialyzer and Asahi Rexeed 25S and raises no new types of safety or effectiveness questions.

8. **Does descriptive or performance information demonstrate equivalence?**

YES – Fresenius Medical Care North America believes that the information provided in this submission clearly describes the Fresenius Optiflux F250NR and that the performance characteristics and other information supplied demonstrate that it is substantially equivalent to the Baxter Xenium dialyzer and Ashai Rexeed 25S.

F. Safety Summary

The Fresenius Optiflux® F250NR dialyzer is substantially equivalent in construction, design, materials, and intended use to the commercially available Baxter Xenium 210 and Asahi Rexeed 25S dialyzer. In addition, testing of the Fresenius Optiflux F250NR dialyzer indicates that it is safe and effective for its intended use.

Fresenius Medical Care

Fresenius Optiflux® F250NR Dialyzer
510(k) Summary

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 Fresenius F250NR dialyzer.

Janet C Kay

Janet C. Kay RAC,
Regulatory Affairs Manager

19-Aug-2008

Date

RQ 8-20-08

~~55~~ 6 ~~126~~
56

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 2008

Janet C. Kay, RAC
Regulatory Affairs Manager
Fresenius Medical Care North America
920 Winter Street
WALTHAM MA 02451

Re: K082414
Trade/Device Name: Fresenius Optiflux® F250NR Dialyzer
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: August 20, 2008
Received: August 21, 2008

Dear Ms. Kay:

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 such 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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K082414 page 1 of 1

Confidential

Fresenius Medical Care
Fresenius Optiflux® F250NR Dialyzer

Device Name:

Fresenius Optiflux® F250NR Dialyzer

Indications for Use:

The Fresenius Optiflux® F250NR dialyzers are intended for 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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082414

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

Fresenius Medical Care North America
Corporate Headquarters: 920 Winter Street Waltham, MA 02451-1457 781-699-9000