MAR 16 2000

Fresenius 2008K
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) 402-9082
Contact Person:	Arthur Eilinsfeld, Regulatory Affairs Manager
Date of Preparation:	December 10, 1999

B. Device Name:

Trade Name:	Fresenius 2008K Dialysate Delivery System
Common/Usual Name:	Hemodialysis Delivery Equipment
Classification Name:	Sealed Dialysate Delivery System

C. Predicate Device Name:

- Fresenius 3008 Dialysate Delivery System (#K921456, 4/20/94)

D. Device Description/Indications for Use:

The indications for use for the Fresenius 2008K are identical to those of the Fresenius 3008 and are as follows:

The Fresenius 2008K is indicated for acute and chronic dialysis therapy.

Fresenius 2008K
510(k) Premarket Notification

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E. Substantial Equivalence:

510(k) Substantial Equivalence Decision Making Process

1. Is the product a device?

YES - The Fresenius 2008K is a device pursuant to 21 CFR §201 [321] (h).

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

YES – The intended use for the Fresenius 2008K is the same as that for the Fresenius 3008 and is as follows:

Intended Use

The Fresenius 2008K is indicated for acute and chronic dialysis therapy.

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

NO – The technological characteristics of the Fresenius 2008K are equivalent to those of the Fresenius 3008. Both the Fresenius 2008K and the Fresenius 3008 proportion concentrate and prepare and deliver deaerated dialysate fluid at the desired conductivity, temperature and specified pressure. The ultrafiltration control method is identical in both the Fresenius 2008K and the Fresenius 3008, which control ultrafiltration during dialysis by withdrawing a defined volume of fluid from the closed dialysate circuit. The primary difference between the Fresenius 2008K and the 3008 is the new user interface.

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 Fresenius 2008K and demonstrates that it is substantially equivalent to the Fresenius 3008.

Fresenius 2008K
510(k) Premarket Notification

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F. Safety Summary

The Fresenius 2008K software validation, functional testing, and release testing rigorously tested the features of the 2008K. The results of this testing indicate that the Fresenius 2008K is safe and effective for its intended use.

G. General Safety and Effectiveness Concerns

The device labeling contains an Operator's Manual, which includes indications for use, cautions and warnings, as well as the general operating instructions required for proper use of the device. In addition, training and support is provided to clinics that use the Fresenius 2008K. This information promotes safe and effective use of the device.

Arthur Eilinsfeld
Regulatory Affairs Manager

12/16/99
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2000

Arthur Eilinsfeld
Regulatory Affairs Manager
Fresenius Medical Care, North America
Two Ledgemont Center
95 Hayden Avenue
Lexington, Massachusetts 02420

Re: K994267
Fresenius 2008K Dialysate Delivery System
Dated: December 16, 1999
Received: December 17, 1999
Regulatory Class: III
21 CFR §876.5860/Procode: 78 KDI

Dear Mr. Eilinsfeld:

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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Fresenius Medical Care

Indications for Use Statement

Device Name:

Fresenius 2008K Dialysate Delivery System

Indications for Use:

The Fresenius 2008K is indicated for acute and chronic dialysis therapy.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994267