APR 24 2007

Fresenius Medical Care
Fresenius Renal Acute Care (RAC 100) Filter
510(k) Summary

This 510(k) Summary 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:	Fresenius Renal Acute Care (RAC 100) Filter
Common Name:	Dialyzer, High Permeability with or without Sealed Dialysate System
Product Code/Classification Panel:	78KDI/Gastroenterology-Urology
Classification:	Class II per §876.5860

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C. Predicate Devices

The Fresenius Renal Acute Care (RAC 100) Filter is substantially equivalent to the Fresenius Optiflux F160NR, Gambro Hospal Multiflow 100 Hemofilter and the Gambro M100 Hemofilter.

Gambro Hospal Multiflow 100:

- K980386 (2/24/99)

Gambro M100

- K032431 (9/15/03)

Optiflux F160NR

- K003498 (1/4/01)

D. Indications for Use/Intended Use:

Intended for use in removing solutes or fluid in renal supportive therapies in an acute setting. This filter can be used for intermittent and continuous therapies.

The RAC 100 Filter is intended for use in the following continuous veno-venous therapies:

- continuous veno-venous hemofiltration (CVVH)
- continuous veno-venous hemodialysis (CVVHD)

The RAC 100 Filter is intended for use in the following intermittent therapies, e.g. slow low efficiency dialysis (SLED) or other renal supportive therapies of less than 8 hours duration.

E. Substantial Equivalence:

1. **Is the product a device?**

YES - The Fresenius Renal Acute Care (RAC 100) Filter is a device pursuant to 21 CFR §201 [321] (h).

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

YES – The intended use for the Fresenius Renal Acute Care Filter is equivalent to that of the Gambro Hospal Multiflow 100 Hemofilter, Gambro M100 Hemofilter.

Fresenius Renal Acute Care Filter - Intended Use

Intended for use in removing solutes or fluid in renal supportive therapies in an acute setting. This filter can be used for intermittent and continuous therapies.

The RAC 100 Filter is intended for use in the following continuous veno-venous therapies:

- continuous veno-venous hemofiltration (CVVH)
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Gambro Hospal Multiflow 100 - Intended Use

The Hospal Multiflow 100 is indicated for use whenever continuous veno-venous hemofiltration or hemodialysis is indicated. This can be used for acute hemodialysis and hemofiltration. In these therapies, monitoring of patient vital signs, the therapy delivery system, heparin administration, and clotting times should be performed under the direction of a physician.

Gambro M100 – Intended Use

Indicated for use with the Prisma Control Unit in providing continuous fluid management and renal replacement therapies for patients who have acute renal failure, fluid overload, or both.

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

   NO –The technological characteristics of the Fresenius Renal Acute Care (RAC 100) Filter are equivalent to those of the Fresenius Optiflux F160NR, Gambro Hospal Multiflow 100 Hemofilter and the Gambro M100 Hemofilter 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 Fresenius Renal Acute Care (RAC 100) Filter and that the performance characteristics and other information supplied demonstrates that it is substantially equivalent to the Fresenius Optiflux F160NR, Gambro Hospal Multiflow 100 Hemofilter and the Gambro M100 Hemofilter.

F. Safety Summary

The Fresenius Renal Acute Care (RAC 100) Filter is substantially equivalent in construction, design, materials, and intended use to the commercially available Fresenius Optiflux F160NR, Gambro Hospal Multiflow 100 Hemofilter and the Gambro M100 Hemofilter. In addition, testing of the Fresenius Renal Acute Care (RAC 100) Filter indicates that it is safe and effective for its intended use.

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 Renal Acute Care (RAC 100) Filter.

Janet C Kay

Janet C. Kay RAC,
Regulatory Affairs Manager

4/19/07

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Janet C. Kay
Regulatory Affairs Manager
Fresenius Medical Care North America
920 Winter Street
WALTHAM MA 02451-1457

APR 24 2007

Re: K070222
Trade/Device Name: Fresenius Renal Acute Care (RAC 100) Filter
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: January 23, 2007
Received: January 24, 2007

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 (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 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/industry/support/index.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 Renal Acute Care (RAC 100) Filter

Device Name:

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Indications for Use:

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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

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070222