K042938
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510(K) SUMMARY

SUBMITTER:

Gambro Renal Products
10810 West Collins Avenue
Lakewood, CO 80215
USA

CONTACT:

Thomas B. Dowell, Manager Regulatory Affairs
Phone: (303) 231-4094
Fax: (303) 542-5138

DATE PREPARED: October 21, 2004

DEVICE NAME:

Prismaflex HF 1000 Set
Prismaflex HF 1400 Set

COMMON/UNUSUAL NAME:

Hemofilter and Blood Tubing Set
High Permeability Hemodialyzer

CLASSIFICATION NAMES: High Permeability Hemodialysis System Accessory

CLASSIFICATION PANEL: KDI Gastroenterology - Urology

CLASSIFICATION: Class II per 21 CFR 876.5860

PREDICATE DEVICES:

Gambro Prisma HF1000 Set	K011221
Gambro Prismaflex M60/M100 Set	K041005

SUBSTANTIAL EQUIVALENCE:

The proposed Prismaflex HF 1000 and HF 1400 sets are substantially equivalent to the Prisma HF 1000 sets and Prismaflex M60/M100 sets currently on the market. The modifications in the proposed devices are substantially equivalent in design, function, composition, and operation, to the predicate devices that have FDA clearance under 510(k)'s K011221 and K041005.

DEVICE DESCRIPTION:

The Prismaflex disposable sets are sterile disposable extracorporeal circuits containing a PAES hemofilter/dialyzer and fluid circuit for use with the Prismaflex control Unit. These Prismaflex disposable sets allow the following fluid management and renal replacement therapies to be performed:

- SCUF : Slow Continuous Ultrafiltration
- CVVH : Continous Veno-Venous Hemofiltartion
- CVVHD : Continous Veno-Venous Hemodialysis
- CVVHDF : Continuous Veno-Venous Hemodiafiltartion

INDICATIONS FOR USE:

The Prismaflex Set is indicated for use only with the Prismaflex Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

TECHNOLOGICAL CHARACTERISTICS:

The proposed device configurations have the same technological characteristics and are similar in design, function, and operation, to the currently marketed configurations.

SUMMARY OF NON-CLINICAL TESTS and CONCLUSION:

In vitro testing was conducted to compare the performance of the proposed device configurations to the predicate configurations. The results of the in vitro testing demonstrate that the proposed configurations are substantially equivalent to the predicate configurations and are suitable for the intended use.

SUMMARY OF CLINICAL TESTS and CONCLUSION:

Not applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 2005

Mr. Thomas B. Dowell
Manager Regulatory Affairs
Gambro® Renal Products
10810 W. Collins Avenue
LAKEWOOD CO 80215

Re: K042938
Trade/Device Name: Prismaflex™ HF 1000 Set and Prismaflex™ HF 1400 Set
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: December 16, 2004
Received: December 17, 2004

Dear Mr. Dowell:

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 STATEMENT

510(k) Number (if known): K042938

Device Name:

Prismaflex™ HF 1000 Set
Prismaflex™ HF 1400 Set

Indications For Use:

The Prismaflex Set is indicated for use only with the Prismaflex Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042938