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510(k) Summary

Submitter: Gambro Renal Products, Inc.
14143 Denver West Parkway
Lakewood, Colorado 80401

JUN 13 2008

Contact: Kae Miller, Manager, Regulatory Affairs

Phone: 303-542-5045
Fax: 303-876-9264

Date prepared: February 22, 2008

Device name: Prismaflex M150 Set

Common name: Hemofilter and Blood Tubing Set
High Permeability Hemodialyzer

Classification names: High Permeability Hemodialysis System Accessory (876.5860)

Classification panel KDI Gastroenterology - Urology

Classification Class II per 21 CFR 876.5860

Predicate Devices:

Gambro Prismaflex M100 Set K041005

Substantial Equivalence: The proposed Prismaflex M150 Set is substantially equivalent to the Prismaflex M100 set currently on the market. The modifications in the proposed device are substantially equivalent in design, function, composition, and operation, to the predicate device that has FDA clearance under 510(k) K041005.

Device Description: The Prismaflex disposable sets are sterile disposable extracorporeal circuits containing an AN69 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: Continuous Veno-Venous Hemofiltration
- CVVHD: Continuous Veno-Venous Hemodialysis
- CVVHDF: Continuous Veno-Venous Hemodiafiltration

Indications For Use: The Prismaflex M150 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.

K080519

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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: 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 used.

Summary of Clinical Tests: Not applicable.

Conclusion: Testing performed on Prismaflex M150 Set demonstrates that it is safe, effective and performs as well as the predicate devices, when used in accordance with instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2008

Ms. Kae Miller
Manager, Regulatory Affairs
Gambro Renal Products, Inc.
14143 Denver West Parkway
LAKEWOOD CO 80401

Re: K080519
Trade/Device Name: Prismaflex M150 Set
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: April 11, 2008
Received: April 14, 2008

Dear Ms. Miller:

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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (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,

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

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Indications for Use Statement

510(k) number:
(if known) K080519

Device Name: Prismaflex M150 Set

Indications for Use: The Prismaflex M150 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 ___X___ (Per 21 CFR 801 Subpart D) AND / OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(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 K080519