K072093
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5.0 510(K) SUMMARY

Submitter's Name	Gambro
Address	14143 Denver West Parkway Lakewood, Colorado 80401
Establishment Registration Number	2087532
Date of Summary	July 27th, 2007
Telephone Number **Fax Number**	(303) 231-4094 (303) 542-5138
Contact Person	Thomas B. Dowell, Regulatory Affairs Project Manager
Name of the Device	Prismaflex® System 3.20 Catalogue Number: 107493
Common or Usual Name	Hemodialysis Delivery System
Classification Name	Classification Name: High Permeability Hemodialysis System Device Class: II Product Code: 78KDI Regulation Number: 876.5860
Indications for Use	The Prismaflex® System is intended for Continuous Renal Replacement Therapy (CRRT) for patients with acute renal failure and/or fluid overload weighing 20 Kilograms or more. All treatments administered via the Prismaflex® must be prescribed via a physician.
Identification of the Legally Marketed Device (Predicate Device)	Prismaflex™ System 1.04 Catalogue Number: 6023014700 Classification Name: High Permeability Hemodialysis System Device Class: II Product Code: 78KDI Regulation Number: 876.5860

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Gambro
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510(k) SUMMARY, continued

Device Description

The Prismaflex® System is intended for Continuous Renal Replacement Therapy (CRRT) for patients with acute renal failure and/or fluid overload weighing 20 Kilograms or more. All treatments administered via the Prismaflex® must be prescribed via a physician. The goals of acute renal failure treatments are removal of waste products, restoration of acid-base balance; correction of electrolyte imbalances (e.g., hyperkalemia), patient fluid balance, nutritional support, and other conditions in which fluid removal is needed. Prismaflex® System offers four Continuous Renal Replacement Therapy (CRRT) options: Slow Continuous Ultrafiltration (SCUF), Continuous Veno-Venous Hemofiltration (CVVH), Continuous Veno-Venous Hemodialysis (CVVHD), and Continuous Veno-venous Hemodialfiltration (CVVHDF).

Device Comparison Table

	PREDICATE Prismaflex™ System 1.04	**MODIFIED DEVICE** Prismaflex® System 3.20
Indication for Use	The Prismaflex™ is indicated for continuous solute and/or fluid removal in patients with acute renal failure or fluid overload. All treatments administered by the Prismaflex™ must be prescribed by a physician.	The Prismaflex® System is intended for Continuous Renal Replacement Therapy (CRRT) for patients with acute renal failure and/or fluid overload weighing 20 Kilograms or more. All treatments administered via the Prismaflex® must be prescribed via a physician.
Dedicated Disposable Sets Available in U.S.	M60/M100 HF1000 & HF1400	M60/M100 HF1000 & HF1400
Syringe	10, 20 & 30 ml	10, 20, 30 & 50 ml
Anticoagulation	User-controllable as continuous or bolus	User-controllable as continuous or bolus
Dialysate Flow Rate	CVVHD: 0 to 8000 ml/hr CVVHDF: 0 to 4000 ml/hr Increment: 50 ml/hr	CVVHD & CVVHDF 0 to 8000 ml/hr Increment: 50 ml/hr
Dialysate Flow Rate Accuracy	±10% of user-set rate	± 30 ml/hr
Replacement Flow Rate	CVVH: 0 to 8000 ml/hr CVVHDF: 0 to 4000 ml/hr Increment: 50 ml/hr increment	CVVH & CVVHDF: 0 to 8000 ml/hr Increment: 50 ml/hr
Replacement Flow Rate Accuracy	±10% of user-set rate	± 30 ml/hr

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	PREDICATE Prismaflex™ System 1.04	**MODIFIED DEVICE** Prismaflex® System 3.20
Blood Flow Rate	10-450 ml/min. Flow rate depends on the Prismaflex therapy/set combination selected by operator	10-450 ml/min. Flow rate depends on the Prismaflex therapy/set combination selected by operator
Blood Flow Rate Accuracy	±10% of user set point Accuracy of blood flow is maintained if the inlet pressure is higher (less negative) than -250 mmHg and the outlet pressure is lower than +350 mmHg	±10% of user set point Accuracy of blood flow is maintained if the inlet pressure is higher (less negative) than -250 mmHg and the outlet pressure is lower than +350 mmHg
Pre-Blood Pump Flow Rate	SCUF: 0 to 1,000 ml/hr CVVH, CVVHD, CVVHDF: 0 to 8,000 ml/hr	SCUF: 0 to 1,000 ml/hr CVVH, CVVHD, CVVHDF: 0 to 8,000 ml/hr
Pre-Blood Pump Accuracy	±10% of user-set rate	± 30 ml/hr
Effluent Pump Flow Rate	0 to 10,000 ml/hr depending on the therapy	0 to 10,000 ml/hr depending on the therapy
ECG Discharger	YES	YES
Therapies	SCUF CVVH CVVHD CVVHDF	SCUF CVVH CVVHD CVVHDF
Pumps	Blood access line Dialysate inlet line Effluent outlet line Replacement solution line Pre blood pump line	Blood access line Dialysate inlet line Effluent outlet line Replacement solution line Pre blood pump line
Scales	Dialysate Replacement Effluent Pre blood pump	Dialysate Replacement Effluent Pre blood pump

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Lakewood, Colorado 80401

	PREDICATE Prismaflex™ System 1.04	**MODIFIED DEVICE** Prismaflex® System 3.20
Transmembrane Pressure	User settable: +70 to +300 mmHg Default: +300 mmHg	User settable: +70 to +300 mmHg Default: +300 mmHg
Dialysate Conductivity and Temperature	Dialysate Conductivity and Temperature are not controlled by Prismaflex	Dialysate Conductivity and Temperature are not controlled by Prismaflex
Patient Fluid Removal Performance Range	0 to 2,000 ml/hr Increment: 10 ml/hr	0 to 2,000 ml/hr Increment: 10 ml/hr
Patient Fluid Removal Performance Range Accuracy	± 30 ml/hr ± 600 ml/24hr Scales calibrated at ambient temperature at which they will be used. Ambient temperature change less than ± 3° C (5.4 °F) during treatment.	± 30 ml/hr ± 70 ml/3hr ± 300 ml/24hr Scales calibrated at ambient temperature at which they will be used. Ambient temperature change less than ±3°C (5.4 °F) during treatment.
Access Pressure and Return Pressure	Access Pressure: -250 to +300 mmHg Return Pressure: -50 to +350 mmHg	Access Pressure: -250 to +300 mmHg Return Pressure: -50 to +350 mmHg
Access Pressure and Return Pressure Accuracy	±10% of reading or ± 8mmHg (whichever is greater)	±10% of reading or ± 8mmHg (whichever is greater)

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510(k) SUMMARY, continued

Description and Conclusion of Testing

Non-clinical Testing:
The non-clinical testing performed for the Prismaflex® System 3.20 includes component level hardware testing, testing required to support the declarations of conformity to standards contained in this 510(k) submission, testing required by process to ensure compliance with other international standards applicable to hemodialysis machines as well the static and dynamic software testing, e.g. unit testing, code inspections, testing targeted to the changes implemented in software version 3.20, regression testing, human factors evaluations and testing that was performed by internal and external independent personnel with the appropriate skills.

Conclusion:
The successful non-clinical testing demonstrates the safety and effectiveness of the Prismaflex® System when used for the defined indications for use and demonstrates that the device for which the 510(k) is submitted performs as well as or better than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2008

Mr. Thomas B. Dowell
Regulatory Affairs Project Manager
GAMBRO
14143 Denver West Parkway
LAKEWOOD CO 80401

Re: K072093
Trade/Device Name: Prismaflex® System 3.20
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: December 21, 2007
Received: December 26, 2007

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 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

Indications for Use

510(k) Number (if known): K072093

Device Name: Prismaflex® System 3.20

Indications for Use:

The Prismaflex® System is intended for Continuous Renal Replacement Therapy (CRRT) for patients with acute renal failure and/or fluid overload weighing 20 Kilograms or more. All treatments administered via the Prismaflex® must be prescribed via a physician.

Prescription Use ___X____ (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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072093