K110823

Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
Lakewood, CO 80401

Traditional 510(k) for the
Prismaflex® System

JUN 17 2011

5.0 510(k) SUMMARY

Submitter's Name	Gambro Renal Products, Inc.
Address	14143 Denver West Parkway, Suite 400 Lakewood, Colorado 80401
Establishment Registration Number	2087532
Contact Person	Kae Miller Regulatory Affairs Manager, Americas
Telephone Number	303.222.6724
Fax Number	303.222.6916
Date of Summary	March 21, 2011

Device under clearance	
Name of the Device	Prismaflex® Catalogue Number: 113081
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

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510(k) SUMMARY, continued

Predicate Device Information (1)	
Name of the Device	Prisma System R 03.10A
Catalogue Number:	018089-507
510(k) Number:	K062090
Classification Name	High Permeability Hemodialysis System
Device Class	II
Product Code	78KDI
Regulation Number	876.5860

Predicate Device Information (2)	
Name of the Device	Prismaflex® System 3.20
Catalogue Number:	107493
510(k) Number:	K072093
Classification Name	High Permeability Hemodialysis System
Device Class	II
Product Code	78KDI
Regulation Number	876.5860

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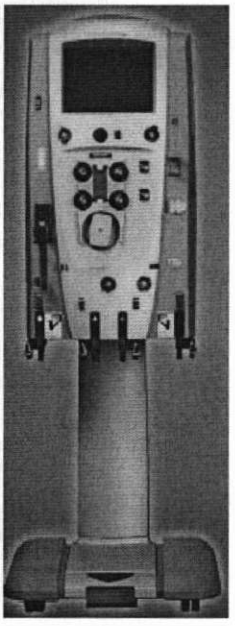
Traditional 510(k) for the
Prismaflex® System

510(k) SUMMARY, continued



DEVICE DESCRIPTION:

The Prismaflex control unit is a software controlled device that performs the following functions:

- Loads and primes the Prismaflex disposable set automatically.
- Pumps blood through the blood flow path of the Prismaflex disposable set.
- Delivers anticoagulant solution into the blood flow path.
- Pumps sterile infusion solutions into the blood flow path of the Prismaflex disposable set according to therapy in use.
- Pumps sterile dialysate into the fluid compartment of the filter in CRRT therapies.
- Controls the patient fluid removal or plasma loss according to the therapy in use.
- Monitors the system and alerts the operator to abnormal situations through alarms.

The Prismaflex® has a touch screen user interface that provides operating instructions.

The Prismaflex® provides color coding and bar-code identification of the filter sets that are automatically loaded. The Prismaflex continually monitors the operation of the machine and displays one of four (4) types of alarms if an abnormal situation occurs. The Prismaflex® has five (5) pumps that allow multiple therapeutic combinations; including a "pre-blood pump" that allows infusion of a supplemental solution for hemodilution or anticoagulation of the extracorporeal circuit.

PHYSICAL CHARACTERISTICS OF PRISMAFLEX®:

WEIGHT:	Approximately 60 kg (132 lb) without fluid bags and Prismaflex disposable set
HEIGHT:	Approximately 162 cm (64 in)
WIDTH:	Approximately 49 cm (19 in)
BASE:	Approximately 60 cm x 63 cm (24 in x 25 in)

INDICATIONS FOR USE:

The Prismaflex® control unit is intended for:

- Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload.
- Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated.

All treatments administered via the Prismaflex® control unit must be prescribed by a physician

510(k) SUMMARY, continued

5.1 Device Comparison Table

In the following table the Prismaflex® with software version 5.10 is compared for the TPE therapy with the predicate Prisma System R 03.10A and for the CRRT therapies with the predicate Prismaflex® System 3.20.

	DEVICE Prismaflex®	**PREDICATE** [for TPE] Prisma System R 03.10A	**PREDICATE** [for CRRT] Prismaflex® System 3.20
Indication for Use	The Prismaflex control unit is intended for: • Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload. • Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated. All treatments administered via the Prismaflex control unit must be prescribed by a physician.	The Prisma System is indicated for continuous solute and/or fluid removal in patients with acute renal failure or fluid overload and for therapeutic plasma exchange in patients with disease where removal of plasma components is indicated.	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.	For CRRT: M60/M100/M150 HF1000 & HF1400 For TPE: TPE 2000 Set	Gambro TPE Set with Plasmafilter PF2000N	M60/M100 HF1000 & HF1400
Syringe	10,20,30 & 50 ml	20 ml	10, 20, 30 & 50 ml

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	DEVICE Prismaflex®	**PREDICATE** [for TPE] Prisma System R 03.10A	**PREDICATE** [for CRRT] Prismaflex® System 3.20
Anticoagulation	User-controllable as continuous or bolus	Delivered continuously or in bolus	User-controllable as continuous or bolus
Dialysate Flow Rate	CVVH & CVVHDF: Range: 0 to 8000 ml/hr Increment: 50 ml/hr	Not for TPE.	CVVHD & CVVHDF: Range: 0 to 8000 ml/hr Increment: 50 ml/hr
Dialysate Flow Rate Accuracy	± 30 ml/hr	Not for TPE.	± 30 ml/hr
Replacement solution / Fluid Flow Rate	CVVH & CVVHDF: Range: 0 to 8000 ml/hr Increment: 50 ml/hr TPE: Range: 0 to 5000 ml/hr Increment: 10 ml/hr	TPE: up to 2000 ml/hr.	CVVH & CVVHDF: Range: 0 to 8000 ml/hr Increment: 50 ml/hr
Replacement Flow Rate Accuracy	± 30 ml/hr	± 30 ml/hr	± 30 ml/hr
Blood Flow Rate	Range: 10-450 ml/min.	Up to 180 ml/min.	Range: 10-450 ml/min. Flow rate depends on the Prismaflex therapy/set combination selected by operator
Blood Flow Rate Accuracy	±10% of user set rate The accuracy of blood flow is maintained if: – the inlet pressure is higher (less negative) than –250 mmHg; – the outlet pressure is lower than +350 mmHg	±25% of user set rate.	±10% of user set point Treatment time up to 72 hours

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	DEVICE Prismaflex®	**PREDICATE** [for TPE] Prisma System R 03.10A	**PREDICATE** [for CRRT] Prismaflex® System 3.20
Pre-Blood Pump Flow Rate	**SCUF, TPE:** Range: 0 to 1000 ml/hr Note: Total PBP Volume is 2000 ml/treatment for TPE **CVVH, CVVHD, CVVHDF:** Range: 0 to 4000 ml/hr	This pump is not available with Prisma	SCUF: 0 to 1000 ml/hr CVVH, CVVHD, CVVHDF: 0 to 8000 ml/hr
Pre-Blood Pump Accuracy	± 30 ml/hr	This pump is not available with Prisma	± 30 ml/hr
Effluent Pump Flow Rate	0 to 10000 ml/hr depending on the therapy	0, or 1000 to 5500 ml/hr	0 to 10000 ml/hr depending on the therapy
ECG Discharger	YES	Electrodes with low contact impedance are required	YES
Therapies	SCUF CVVH CVVHD CVVHDF TPE	SCUF CVVH CVVHD CVVHDF TPE	SCUF CVVH CVVHD CVVHDF
Pumps	PBP solution Replacement solution Dialysate solution Effluent Blood	Dialysate Replacement Effluent Blood	PBP solution Replacement solution Dialysate solution Effluent Blood
Scales	Dialysate Replacement Effluent Pre blood (PBP)	Dialysate Replacement Effluent	Dialysate Replacement Effluent Pre blood

	DEVICE Prismaflex®	**PREDICATE** [for TPE] Prisma System R 03.10A	**PREDICATE** [for CRRT] Prismaflex® System 3.20
Transmembrane Pressure TMP (CRRT) TMPa (TPE)	TMP: User settable: +70 to +350 mmHg Default: +350 mmHg TMPa: User settable; +50 to +100 mmHg Default: +100 mmHg	TMPa: User settable: 0 to +100 mmHg Default: +100 mmHg	TMP: 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 Prisma	Dialysate Conductivity and Temperature are not controlled by Prismaflex
Patient Fluid Removal Performance Range	0 to 2000 ml/hr maximum for **CRRT** 0 to 1000 ml/hr for **TPE** Increment: 10 ml/hr	0 to 2000 ml/hr Increment: 10 ml/hr	0 to 2000 ml/hr Increment: 10 ml/hr
Patient Fluid Removal Performance Range Accuracy	± 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.	± 30 ml/hr Scales calibrated at ambient temperature at which they will be used. Ambient temperature change less than ±1°C (5.4 °F) during treatment. ± 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.	± 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 +50 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 ± 8 mmHg whichever is greater	±10% of reading or ± 8 mmHg (whichever is greater)	±10% of reading or ± 8 mmHg (whichever is greater)

	DEVICE Prismaflex®	**PREDICATE** [for TPE] Prisma System R 03.10A	**PREDICATE** [for CRRT] Prismaflex® System 3.20
TPE Settings:	Pre-treatment Hematocrit Range: 10 to 60% Increment: 1% Default: 30%	Pre-treatment Hematocrit Range: 10 to 60% Increment: 1% Default: 43%	N/A for CRRT.
	Total Replacement Volume Range: 0 to 10,000 ml Increment: 100 ml Default: 3000 ml	Total Replacement Volume Range: 0 to 10,000 ml Increment: 100 ml Default: 3000 ml	N/A for CRRT
	Patient Plasma Loss Rate Range: 0, or 10 to 1000 ml/hr Increment: 10 ml/hr Default: 0 ml/hr	Patient Plasma Loss Rate Range: 0, or 10 to 1000 ml/hr Increment: 10 ml/hr Default: 0 ml/hr	N/A for CRRT
	Replacement Container Volume Range: 0 to 5000 ml Increment: 10 ml	Replacement Container Volume Range: 0 to 5000 ml Increment: 10 ml	N/A for CRRT

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510(k) SUMMARY, continued

Assessment of performance data

The testing performed for the Prismaflex® equipped with software version 5.10, in order to determine the substantial equivalence with predicate devices included:

- Complete software and system verification and validation including functional, performance and safety requirements;
- Compliance has been demonstrated to the following international standards;
    - IEC 60601-1: Medical electrical equipment: Part 1: General requirements for safety
    - IEC 60601-1-1: Medical electrical equipment: Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
    - IEC 60601-1-2: Medical electrical equipment: Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
    - IEC 60601-1-4: Medical electrical equipment: Part 1-4: General requirements for Collateral Standard: Programmable electrical Medical Systems
    - IEC 60601-2-16: Medical electrical equipment - Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment

Conclusion

The successful testing of the Prismaflex® equipped with software version 5.10 demonstrates safety and effectiveness when used for the defined indications for use and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Kae Miller
Regulatory Affairs Manager
Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
LAKEWOOD CO 80401

JUN 17 2011

Re: K110823
Trade/Device Name: Prismaflex®
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: March 21, 2011
Received: March 24, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110823

Device Name: Prismaflex®

Indications for Use:

The Prismaflex® control unit is intended for:

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All treatments administered via the Prismaflex® control unit must be prescribed by a physician.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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, Gastro-Renal, and Urological Devices
510(k) Number K110823