K062090
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Gambro Renal Products
10810 West Collins Avenue
Lakewood, CO 80215

12.0 510(k) SUMMARY

OCT 18 2006

Submitter's Name	Gambro Renal Products
Address	10810 West Collins Avenue Lakewood, CO 80215
Establishment Registration Number	1713683
Date of Summary	July 23, 2006
Telephone Number **Fax Number**	(303) 231-4094 (303) 542-5138
Contact Person	Thomas B. Dowell, Manager Regulatory Affairs
Name of the Device	Prisma® R03.10A System Catalogue Number: 018089-507
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 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.
Identification of the Legally Marketed Device (Predicate Device)	Prisma® 3.03 System Catalogue Number: 018089-507 Classification Name: High Permeability Hemodialysis System Device Class: II Product Code: 78KDI Regulation Number: 876.5860

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Device Description

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. All treatment administered via the Prisma® System must be prescribed by a physician. The Prisma® System is designed for use on critically ill patients in the intensive care unit to provide the following treatments: SCUD (slow Continuous Ultrafiltrtion), CVVH (Continuous Veno-Venous Hemofiltration), CVVHD (Continuous Veno-Venous Hemodialysis), CVVHDF (Continuous Veno-venous Hemodialfiltration) and TPE (Therapeutic Plasma Exchange).

The Prisma® System consists of the Prisma Control Unit and a series of disposable extracorporeal blood circuits (Prisma Sets) to allow four types of continuous renal replacements therapies as well as therapeutic plasma exchange (TPE) therapy. The blood circuit utilized will be dependent on the individual patient's therapy and needs.

The Prisma Control Unit performs the following functions:

1. Loads and primes the Prisma Set automatically.
2. Pumps blood through the blood flowpath of the set.
3. Delivers anti-coagulant solution into blood flowpath.
4. Controls fluid removal/plasma loss from the patient.
5. Pumps sterile replacement solution/fluid and/or sterile dialysate. Pumps effluent.
6. Monitors the system and alerts the operator to abnormal situations through alarms.

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510(k) SUMMARY, continued

Comparison Table

	PREDICATE Prisma® System V 3.03	**MODIFIED DEVICE** Prisma® System R03.10A
Indication for Use	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 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
Dedicated Disposable Sets	M60/M100 (K032431), 66D pre and post dilution sets, PF2000N (PMA P830063) HF1000	M60/M100 (K032431), 66D pre and post dilution sets, PF2000N (PMA P830063) HF1000
Replacement Solutions Used	Sterile commercial fluid labeled for intravenous injection or solution prepared in the hospital pharmacy. Prescribed by physician.	Sterile commercial fluid labeled for intravenous injection or solution prepared in the hospital pharmacy. Prescribed by physician.
Dialysate Solutions Used	AAMI RD-5 Standard dialysate solution, composition prescribed by physician and Prismasate (K013448). None used for TPE.	AAMI RD-5 Standard dialysate solution, composition prescribed by physician and Prismasate (K013448). None used for TPE.
Anticoagulantion	Delivered continuously or in bolus into blood path at a point before blood enters the dialyzer.	Delivered continuously or in bolus into blood path at a point before blood enters the dialyzer.
Fluid Removal Rate from Patient	**SCUF:** up to 2 L/hr. **CVVH:** up to 1 L/hr. **CVVHD:** up to 1 L/hr. **CVVHDF:** up to 1 L/hr. **TPE:** 0 – 1000 ml/hr.	**SCUF:** up to 2 L/hr. **CVVH:** up to 1 L/hr. **CVVHD:** up to 1 L/hr. **CVVHDF:** up to 1 L/hr. **TPE:** 0 – 1000 ml/hr.
Blood Flow Rate	Up to 180 ml/min.	Up to 180 ml/min.
Fluid Replacement Rate	**SCUF:** 0 L/hr. **CVVH:** up to 4.5 L/hr. **CVVHD:** 0 L/hr. **CVVHDF:** up to 2 L/hr. **TPE:** up to 2 L/hr.	**SCUF:** 0 L/hr. **CVVH:** 0, or 0.1 to 4.5 L/hr. **CVVHD:** 0 L/hr. **CVVHDF:** 0, or 0.1 to 2 L/hr. **TPE:** up to 2 L/hr.
Effluent Flow Rate	**SCUF:** up to 2 L/hr. **CVVH:** up to 5.5 L/hr. **CVVHD:** up to 3.5 L/hr. **CVVHDF:** 10-5500 ml/hr **TPE:** up to 3 L/hr.	**SCUF:** up to 2 L/hr. **CVVH:** up to 5.5 L/hr. **CVVHD:** up to 3.5 L/hr. **CVVHDF:** 10-5500 ml/hr **TPE:** up to 3 L/hr.
Primary Solute Removal Mechanism	**SCUF:** Convection **CVVHD:** Convection **CVVHD:** Diffusion **CVVHDF:** Convection & Diffusion **TPE:** Convection	**SCUF:** Convection **CVVHD:** Convection **CVVHD:** Diffusion **CVVHDF:** Convection & Diffusion **TPE:** Convection

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	PREDICATE Prisma® System V 3.03	**MODIFIED DEVICE** Prisma® System R03.10A
Transmembrane Pressure	See table below	See table below
Ultrafiltration Rate	Off, 10 – 5500 ml/hr	Off, 10 – 5500 ml/hr
Dialysate Temperature	*N/A: See explanation below	*N/A: See explanation below
Dialysate Conductivity	**N/A: See explanation below	**N/A: See explanation below
Arterial and Venous Pressure	Operating Range -250 to +50 mmHg Accuracy ±10% of reading or ±8 mmHg, whichever is greater	Operating Range -250 to +50 mmHg Accuracy ±10% of reading or ±8 mmHg, whichever is greater

TMP Alarm Limits in Prisma (same for 3_03 & 3_10)

Alarm	Default	Option
"TMP Too High" Advisory Limit	+350 mmHg	+70 to +350 mmHg Increment: 10 mmHg
"Filter Is Clotting" Advisory Limits	Advisory alarm occurs	One or more limits are reached.
a) Filter pressure drop[b] (ΔP filter) variation	100 mmHg	a) User settable: 10 to 100 mmHg greater than initial ΔP. Increment: 10 mmHg
b) TMP increase	Default: 150 mmHg	Service settable: 50 to 200 mmHg greater than initial TMP. Increment: 5 mmHg
Filter Clotted" Warning Limit	Filter pressure minus return pressure is ≥ 250 mmHg OR One or both of the "Filter is Clotting" Advisory Limits are reached *and* TMP is ≥ 450 mmHg.	N/A
"TMP Excessive" Caution Limit	TMP ≥ 450 mmHg	N/A

TMP = (Filter Pressure + Return Pressure)/2 – Effluent Pressure

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* Dialysate conductivity is not applicable because the Prisma does not mix water and concentrates to produce dialysate. There is also no temperature control or monitoring included in Prisma. Accessory warmers for Prisma include appropriate protective measures. There are no conductivity or temperature controls or monitoring.

**The term Access Pressure in Prisma is equivalent to Arterial Pressure; the term Return Pressure in Prisma is equivalent to Venous Pressure. Prisma includes an Effluent Flow Rate in therapies where dialysate is not used, the effluent rate is the ultrafiltration rate (everything pulled in to the effluent bag is coming across the dialyzer membrane). In therapies where there is also a dialysate flow (CVVHD, CVVHDF), the ultrafiltration rate is the difference between effluent rate and the dialysate rate.

TMP (CRRT) and TMPa (TPE) are values calculated from measured pressures. There is no control to TMP (TMPa) in the system, but there are various alarms that are triggered by the calculated TMP.

Description and Conclusion of Testing	**Nonclinical Testing:** The nonclinical testing included unit testing, code inspections, testing targeted to the changes implemented in R03.10A, regression testing and 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 Prisma® R03.10A 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 device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT 1 8 2006

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

Re: K062090
Trade/Device Name: Prisma® R03.10A System
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: July 23, 2006
Received: July 24, 2006

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 (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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (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): K062090

Device Name: Prisma® R03.10A System

Indications for Use:

"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."

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062090