510(K) SUMMARY FOR THE GAMBRO PRISMA M60/M100 SETS

510(k) Number: K032431

SEP 1 5 2003

A. Submitter's Information

Name:	Gambro Renal Products
Address:	10810 West Collins Avenue Lakewood, Colorado 80215 USA
Phone:	303-542-5075
Fax:	303-542-5138
Contact Person:	Rod J. Rylands, Director Regulatory Affairs

B. Device Information

Classification name:	High Permeability Hemodialysis System Accessory [21 CFR 876.5860]
Common or usual name:	Hemofilter and Blood Tubing Set
Proprietary Name(s):	Prisma M60 Post-dilution Prisma M60 Pre-dilution Prisma M60 Pre-Pump Infusion Prisma M100 Post-dilution Prisma M100 Pre-dilution Prisma M100 Pre-Pump Infusion
Product Code Classification Panel:	KDI/Gastroenterology-Urology
Classification:	Class II per 21 CFR 876.5860

C. Predicate Device Information

The predicate devices cleared under 510(k)'s – K946279, K981681, and K980386 are:

Prisma M60 Post-dilution
Prisma M60 Pre-dilution
Prisma M60 Pre-Pump Infusion
Prisma M100 Post-dilution
Prisma M100 Pre-dilution
Prisma M100 Pre-Pump Infusion

D. Substantial Equivalence

The proposed Prisma M60/M100 sets are substantially equivalent to the Prisma M60/M100 sets currently on the market. The modifications in the proposed Prisma M60/M100 sets are substantially equivalent in design, function, composition, and operation, to the Prisma M60/M100 sets that have FDA clearance under 510(k)'s – K946279, K980386, and K981681.

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E. Device Description

The Prisma Disposable Sets are sterile disposable extracorporeal circuits containing an AN 69 HF hemofilter/dialyzer and fluid circuit for use with the Prisma Control Unit. These Prisma Disposable Sets allow the following fluid management and renal replacement therapies to be performed:

SCUF – Slow Continuous Ultrafiltration
CVVH – Continuous Venovenous Hemofiltration
CVVHD – Continuous Venovenous Hemodialysis
CVVHDF – Continuous Venovenous Hemodiafiltration

F. Indications For Use

Indicated for use with the Prisma Control Unit in providing continuous fluid management and renal replacement therapies for patients who have acute renal failure, fluid overload, or both.

G. Technological Characteristics

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

H. Summary of Non-Clinical Tests Submitted 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.

I. Summary of Clinical Tests Submitted - Not Applicable

5 August 2003

Rod J. Rylands
Director Regulatory Affairs
Gambro Renal Products

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 5 2003

Mr. Rod J. Rylands
Director Regulatory Affairs
Gambro Renal Products
10810 W. Collins Avenue
LAKEWOOD CO 80215

Re: K032431
Trade/Device Name: Prisma M60 and M100 Post-dilution, Pre-dilution and Pre-pump Infusion Sets
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: August 5, 2003
Received: August 16, 2003

Dear Mr. Rylands:

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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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) K032431

Device Name *Prisma M60/M100 Disposable Sets*

Indications for Use

Indicated for use with the Prisma Control Unit in providing continuous fluid management and renal replacement therapies for patients who have acute renal failure, fluid overload, or both.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801. 109)

David A. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032431