DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2004

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

Re: K041005
Trade/Device Name: Gambro Prismaflex™ System with M60 and M100 Sets
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: August 10, 2004
Received: August 11, 2004

Dear Mr. Dowell:

This letter corrects our substantially equivalent letter of October 7, 2004 regarding the incorrect product code listed for the Gambro Prismaflex™ System.

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 (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 continue 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 (240) 276-0115. 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 (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

510(k) Number (if known): K041005

Device Name:

Prismaflex™ System
Prismaflex™ M60 Set
Prismaflex™ M100 Set

Indications For Use:

The Prismaflex is indicated for the following use:

- 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.

Prescription Use ✓ (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)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041005

OCT 7 - 2004

510(k) SUMMARY

SUBMITTER: Gambro Renal Products
10810 West Collins Avenue
Lakewood, CO 80215
USA

CONTACT: Thomas B. Dowell, Manager Regulatory Affairs
Phone: (303) 231-4094
Fax: (303) 542-5138

DATE PREPARED: April 16, 2004

DEVICE NAME: Prismaflex System
Prismaflex M60 Set
Prismaflex M100 Set

COMMON/UNUSUAL NAME: Hemodialysis System

CLASSIFICATION NAMES: High Permeability Hemodialysis System

PRODUCT CODE: KDI

CLASSIFICATION PANEL: Gastroenterology – Urology (GU)

CLASSIFICATION: Class II per 21 CFR 876.5860

PREDICATE DEVICES:

Baxter Accura System	K021615
B.Braun Diapact CRRT	K963440
Gambro Prisma System	K010805
Gambro Prisma M60/M100 Sets	K032431

DEVICE DESCRIPTION:

The Prismaflex System is an acute renal failure treatment device for removal of waste products, restoration of acid-base balance, correction of electrolyte imbalances (eg, hyperkalemia), patient fluid balance, nutritional support, and other conditions in which fluid removal is needed. The system consists of a control unit and a sterile disposable extracorporeal circuit with a hemofilter/dialyzer. Prismaflex 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 Hemodiafiltration (CVVHDF).

SCUF - Provides fluid removal by ultrafiltration.
CVVH - Provides convective solute clearance by hemofiltration. Can provide net fluid removal if desired.
CVVHD - Provides diffusive solute clearance by hemodialysis. Can provide net fluid removal if desired.
CVVHDF - Provides solute clearance by both convection and diffusion. Can provide net fluid removal if desired.

The Prismaflex performs the following functions related to the administration of supported therapies:

- Automatically loads the Gambro Cartridge blood tubing/hemofilter set.
- Primes the Gambro Cartridge set. Automatic or Manual priming may be done. Automatic priming uses preset, cartridge-specific settings for UFR, priming volume, and blood pump flow rate. Manual priming allows the operator to manually select and control these priming parameters.
- Pumps blood through the blood flowpath of the Gambro Cartridge and delivers anticoagulant into the blood flowpath. Anticoagulant may be delivered continuously or in bolus amounts via an anticoagulant-filled syringe loaded into the syringe pump or via infusion using the Pre-Blood Pump infusion pump.
- Controls fluid removal from the patient. Calculates and controls the effluent pump rate required to achieve the current *patient Fluid Removal Rate* set by the operator given the settings for the dialysate and/or replacement pump flow(s).
- Delivers sterile replacement solution from pre-prepared bags.
- Pumps dialysate solution from pre-prepared bags.
- Monitors, displays, and charts treatment data.
- Monitors the system and alerts the operator to abnormal situations through alarms. An alarm is indicated by the alarm name and appropriate control buttons appearing on the machine display; by a red or yellow alarm light; and by an audible alarm (beeping sound).
- Provides automatic rinseback of blood in the Gambro Cartridge, if desired. If enabled, Auto Rinseback controls the blood pump rate and saline volume pumped, according to preset values. Manual Rinseback can also return blood, where the operator controls the blood pump and saline volume.
- Records patient prescription data on a removable storage media.

INDICATIONS FOR USE:

The Prismaflex is indicated for the following use:

- 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.

TECHNOLOGICAL CHARACTERISTICS:

The Prismaflex is similar to the cited predicate devices in the ranges for fluid flow rates, patient fluid balance rates, operating pressures, and anticoagulation. Operation of the device and the cited predicates is similar. The number of scales and pumps included in the design varies from device to device, but the resulting performance capabilities are

similar. With respect to the original Prisma, Prismaflex incorporates an additional scale and an additional pump supporting enhanced replacement solution flexibility.

SUMMARY OF NON-CLINICAL TESTS and CONCLUSION:

The Prismaflex was verified & validated by thorough testing to the design specifications. The results of the testing demonstrate that Prismaflex meets the requirements. Additional certification to the following consensus standards was conducted through 3rd party assessments:

- IEC 60601-1 (+ amendments 1 & 2)
- IEC 60601-1-1
- IEC 60601-1-2
- IEC 60601-1-4
- IEC 60601-2-16
- IEC 14971:2000
- ISO/IEC 12207

The Prismaflex M60/M100 disposable cartridge sets were tested to and met the requirements of ISO 10993-1 Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. Further, the sets were tested to and met the AAMI/ISO 1135 Validation and Routine Control of Ethylene Oxide Sterilization. Results of these tests and in-vitro performance tests for the system demonstrate suitability for the intended use.

SUMMARY OF CLINICAL TESTS and CONCLUSION:

Not applicable