K072908
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GAMBRO

FEB 4 2008

510 (k) Summary

Submitted by: Gambro
1845 Mason Avenue
Daytona Beach, FL 32117

Phone: (386) 274-2811

Fax: (386) 274-2833

Contact: Fei Law

Date Prepared: 09/28/2007

Trade Name: PrismaSate

Common Name: Dialysis Solutions for Continuous Renal Replacement Therapy (CRRT)
Ready to Use Sterile Dialysate

Classification Name: Dialysate Concentrate for Hemodialysis (Liquid or Powder) per 21 CFR 876.5820. The Product/Classification Code is KPO.

Equivalent Predicate: PrismaSate Dialysis Solutions for Continuous Renal Replacement Therapy (CRRT)
Gambro Renal Products, K013448

NxStage Pureflow Solutions
NxStage, K042045

Device Description: Gambro PrismaSate solutions are sterile dialysate solutions for use in Continuous Renal Replacement Therapy (CRRT) for the treatment of acute renal failure and in other cases necessitating fluid or solute removal, such as in the case of drug poisoning with dialysable or filterable substances. The solutions are intended to be used in commercially available continuous renal replacement therapy machines as dialysate. A physician prescribes the chemical composition of the solution to be used. The solutions are sterile, and packaged in flexible bags.

Intended Use: Gambro PrismaSate solutions are indicated for use as a dialysate in Continuous Renal Replacement Therapy.

CRRT is used for the treatment of acute renal failure and in other cases necessitating fluid or solute removal, such as in the case of drug poisoning with dialysable or filterable substances. The solutions are perfused through the dialysis fluid compartment of hemofilters/dialyzers. The dialysate is separated from the patient's blood by means of a semi-permeable membrane. Excess waste products, fluids and toxins found in the blood of a patient with acute renal failure pass through the membrane into the dialysate and eventually go to waste. The therapy is aimed at normalizing the blood.

Predicate Device Comparison: The modified PrismaSate Dialysis Solutions for Continuous Renal Replacement Therapy (CRRT) has the same intended use, indication for use, chemical concentration range, and packaging characteristics as the predicate devices. There are no significant technological changes. Based on the above, the device is substantially equivalent to the stated predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 2008

Ms. Fei Law
Quality and Regulatory Manager
U. S. Solutions
Gambro®
1845 Mason Avenue
DAYTONA BEACH FL 32117

Re: K072908
Trade/Device Name: PrismaSate™
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: January 15, 2008
Received: January 28, 2008

Dear Ms. Law:

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

510(k) Number (if known): K072908

Device Name: PrismaSate™

Indications For Use:

Gambro PrismaSate™ solutions are indicated for use as a dialysate in Continuous Renal Replacement Therapy.

Prescription Use ✓

(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, Abdominal, and Radiological Devices
510(k) Number K072908

(Optional Format 3-10-98)