OCT 6 1999

510(k) #: K 993064

510(k) Summary of Safety and Effectiveness Information in Accordance with SMDA 1990

Gambro Renal Care Products
1185 Oak Street
Lakewood, CO 80215
(800) 525-2623

DATE: 9 September, 1999

OFFICIAL CONTACT: William M. Townsend, Sr. Regulatory Specialist

PRODUCT NAME: PRISMA CFM System Modification to Use an Accessory Blood Warmer

PREVIOUS DEVICE CLEARANCE(s): K942679 Date: 2/10/97 (Original)
K981681 Date: 8/11/98 (CVVHDF Mode)

TRADE NAME: Dialyzer, High Permeability With or Without Sealed Dialysate System

CLASSIFICATION NAME: Gastroenterology and Urology
Class III, 78 KDI
21 CFR 876.5860

SUBSTANTIAL EQUIVALENCE TO:

510(k) Number	Applicant	Device
K970253	Gambro Healthcare	COBE Model Centrysystem 3+ Dialysis Delivery Device
K982760	Gambro Healthcare	COBE Model Cx Hemodialysis Delivery System
K970446	Althin Medical	Drake Wilock System 1000 Dialysis Delivery System

DEVICE DESCRIPTION:

In accordance with Section 510(k) of the Food, Drug and Cosmetics Act, Gambro Renal Care Products intends to introduce a modification of the Prisma Continuous Fluid Management System into commercial distribution. The modification creates an accessory sterile extension line that will allow the Prismatherm II Blood Warmer manufactured by Stihler Electronic GmbH (K991159) to be used with the Prisma system during continuous renal replacement therapy. The integration of the Blood Warmer into the Prisma System will provide gentle warming of the treated blood, prior to its return to the patient. No modifications of the Prisma Dialysis Control Unit were made as part of this change. A modification is made to the Prisma Blood Tubing Set that places two luer fittings into the tubing set return line proximal to the air detector. When using the optional Blood Warmer, the user separates the new luer fittings and attaches the new warmer Extension Line. New labeling is created for the Extension Line and the Blood Tubing Set.

SUBSTANTIAL EQUIVALENCE:

In our notification, we demonstrate substantial equivalence to the identified predicate devices by demonstrating that the predicate devices provide solution heating through the use of heaters to warm either the dialysis water or dialysate prior to the solution passing through the dialyzer. The heat exchanger characteristics of the dialyzers cause heating of the patient's blood in the dialyzer. We demonstrated that the modified Prisma system uses similar design, technology and safety systems as the predicate devices to perform heating of the patient blood in the return line. There were no significant new safety and effectiveness issues identified by this modification to the Prisma CFM 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. All treatments administered via the PRISMA System must be prescribed by a physician." The device indications for use do not change as a result of this modification.

SAFETY AND EFFECTIVENESS:

We demonstrate and certify in the notification that a Design Control System is in place that is in compliance with the requirements listed in 21CFR Part 820.30. We further demonstrate that the design control system addresses hazards identified through both information searches and our own Risk Analysis program. A list of all system level verification and validation protocols completed with acceptable, pre-determined results is provided in the notification.

A search of the FDA's MAUDE database and the MEDLINE database were conducted for information on known manufacturer or user problems with the use of solution warmers with dialysis. In most cases, the hazards identified are recognized in the manufacture and use of dialysis therapy devices. We demonstrate in the notification that the new hazards are considered in the design of the modifications to the Prisma System, and that they do not represent significant new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 1999

Mr. William M. Townsend
Senior Regulatory Affairs Specialist
Gambro Renal Care Products
1185 Oak Street
Lakewood, CO 80215-4498

Re: K993064
PRISMA™ Continuous Fluid Management System
Dated: September 9, 1999
Received: September 13, 1999
Regulatory Class: III
21 CFR §876.5860/Procode: 78 KDI

Dear Mr. Townsend:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

9.0 Indications for Use Statement

510(k) Number (if known): K993064

Device Name: **PRISMA™ Continuous Fluid Management 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. All treatments administered via the PRISMA System must be prescribed by a physician."

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David B. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K993064

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)