



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 26, 2014

Gambro Renal Products, Inc.
Kae Miller
Regulatory Affairs Manager
14143 Denver West Parkway, Suite 400
Lakewood, CO 80401

Re: K133807
Trade/Device Name: Molecular Adsorbent Recirculating System (MARS®)
Prismaflex® System
Regulation Number: 21 CFR§ 876.5870
Regulation Name: Sorbent hemoperfusion system
Regulatory Class: III
Product Code: FLD, KDI
Dated: December 23, 2013
Received: December 26, 2013

Dear Kae Miller,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin  Asher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

A1 Indications for Use Statement

1. INDICATIONS FOR USE

510(k) Number (if known): K133807

Device Name: MARS® System

Indications for Use

The MARS is indicated for the treatment of drug overdose and poisonings. The only requirement is that the drug or chemical be dialyzable (in unbound form) and bound by charcoal and/or ion exchange resins.

The MARS is indicated in the treatment of Hepatic Encephalopathy (HE) due to a de-compensation of a chronic liver disease. Clinical trials conducted with MARS treatments in HE patients having a decompensation of chronic liver disease demonstrated a transient effect from MARS treatments to significantly decrease their hepatic encephalopathy scores by at least 2 grades compared to standard medical therapy (SMT).

Contraindication

The MARS® is not indicated as a bridge to liver transplant. Safety and efficacy has not been demonstrated for this indication in controlled, randomized clinical trials. The effectiveness of the MARS device in patients that are sedated could not be established in clinical studies and therefore cannot be predicted in sedated patients.

Device Name: Prismaflex System

Indications for Use

The Prismaflex control unit is intended for:

- Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload.
- Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated.
- Continuous Renal Replacement Therapy (CRRT) in conjunction with the MARS system to conduct MARS treatments for patients weighing 20 kilograms or more.

All treatments administered via the Prismaflex control unit must be prescribed by a physician.

Prescription Use X And/Or Over the Counter Use
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin P. Fisher -S
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