K100364

Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
Lakewood, Colorado 80401

510(K) SUMMARY

NOV - 3 2010

Submitter's Name	Gambro Renal Products, Inc.
Address	14143 Denver West Parkway, Suite 400 Lakewood, CO 80401
Establishment Registration Number	2087532
Date of Summary	February 8, 2010
Telephone Number **Fax Number**	(303) 222-6724 (303) 222-6919
Contact Person	Kae Miller, Regulatory Affairs Manager
Name of the Device	Gambro Cartridge® Blood Set Low Weight – Low Volume Catalogue Number: 003422-520
Common or Usual Name	Extracorporeal blood circuit for hemodialysis
Classification Name	Classification Name: Hemodialysis System and accessories Device Class: II Product Code: FJK Regulation Number: 21 CFR 876.5820
Identification of the Legally Marketed Device (Predicate Device)	Gambro Cartridge® Blood Set Low Weight Catalogue Number: 003412-500 Classification Name: Hemodialysis System and accessories Device Class: II Product Code: FJK Regulation Number: 21 CFR 876.5820

K100364

Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
Lakewood, Colorado 80401

510(k) SUMMARY, continued

Device Description
The Gambro Cartridge® Blood Set Low Weight – Low Volume is single use sterile tubing set employed in the Gambro hemodialysis equipments extracorporeal circulation. It conveys the patient's blood from the arterial-venous access fistula to the dialyzing filter (arterial line) and back after purification (venous line) and it is commonly referred to as bloodline. A Gambro Cartridge® Blood Set Low Weight – Low Volume can be safely connected to hemodialyzers, vascular accesses and various perfusion lines, under the responsibility of the physician in charge.

Indications For Use
The Gambro Cartridge® Blood Set Low Weight-Low Volume is intended for single use in a hemodialysis treatment using the Phoenix® Dialysis Delivery System.

The Low-Weight – Low Volume model is used when a low extra-corporeal blood volume is recommended. The Low Weight – Low Volume model with a priming volume of 40 ml is indicated for patients with a body weight greater than 15 kg and lower or equal to 20 Kg.

Assessment of non-clinical performance data
The non-clinical testing consisted of performance testing (bench) that included testing for integrity of the strength between connections (pressure leak testing), flow rate (endurance testing of the pump segment), endurance testing of injection ports (access sites), priming volume assessment, tensile testing of joints and materials of all tubing segments, pressure transducers testing, tubing clamps testing, hemocompatibility testing, kinking resistance testing, hemodialysis delivery system compatibility, and expiration date testing (materials biocompatibility, performance, packaging integrity testing).

Assessment of clinical performance data
No clinical testing was required or performed in support of this 510(K) submission.

Conclusion
The successful testing demonstrates the safety and effectiveness of the Gambro Cartridge® Blood Sets Low Weight – Low Volume when used for the defined indications for use and demonstrates that the device for which the 510(k) is submitted performs as well as or better than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6
Silver Spring, MD 20993-0002

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

NOV - 3 2010

Re: K100364
Trade/Device Name: Gambro Cartridge® Blood Set Low Weight – Low Volume
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FJK
Dated: October 20, 2010
Received: October 21, 2010

Dear Ms. 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/CDRHOffices/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" (21CFR 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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
Lakewood, Colorado 80401

Indications for Use

510(k) Number (if known): K100364

NOV - 3 2010

Device Name: Gambro Cartridge® Blood Set Low Weight – Low Volume

Indications for Use:

The Gambro Cartridge® Blood Set Low Weight-Low Volume is intended for single use in a hemodialysis treatment using the Phoenix® Dialysis Delivery System.

The Low-Weight – Low Volume model is used when a low extra-corporeal blood volume is recommended. The Low Weight – Low Volume model with a priming volume of 40 ml is indicated for patients with a body weight greater than 15 kg and lower or equal to 20 Kg.

Prescription Use ___X____ (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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K100364