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5.0 510(k) SUMMARY

MAY 0 2 2013

510(k) Summary

Submitter:	Gambro Renal Products, Inc. 14143 Denver West Parkway, Suite 400 Lakewood, Colorado 80401
Contact:	Kae Miller, Regulatory Affairs, Americas Phone: 303.222.6724 Fax: 303.222.6916
Date Prepared:	February 4, 2013
Device Name:	Gambro Revaclear™ 300 and 400 Dialyzer
Common/Classification Name:	Dialyzer, high permeability with or without sealed dialysate system
Regulation Number:	21 CFR 876.5860
Product Code:	KDI
Review Panel:	Gastroenterology / Urology

Predicate Devices:

Polyflux HD-C4 (BIG) (Revaclear Max)	Cleared – April 24, 2006	K060195
Polyflux HD-C4 (Small) (Revaclear)	Cleared – September 7, 2007	K072232

Device Description:
This device is intended for the treatment of chronic and acute renal failure by hemodialysis.

The intended population of this device is identical to those of the Polyflux HD-C4 (BIG), cleared for marketing in the United States under 510(k) notification K060195 and Polyflux HD-C4 (Small), cleared for marketing in the United States under 510(k) notification K072232.

The membrane used in this device is a blend of polyarylethersulfone (PAES) and polyvinylpyrrolidone (PVP), which is equivalent to the membrane utilized in the Gambro Polyflux HD-C4 (BIG) and Polyflux HD-C4 (Small) single use hemodialyzers cleared for marketing in the United States under 510(k) Notifications (K060195 and K072232).

Blood enters a blood inlet port where it is distributed to the hollow fibers. The patient's blood traverses the inside of the hollow fibers and exits the device via a blood exit port. By means of a hydrostatic pressure or transmembrane pressure which is created by a combination of positive and negative pressures across the membrane, plasma water along

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with certain lower and middle molecular weight solutes pass through the membrane and into the dialysate or filtrate compartment of the device. Uremic toxins and waste products are removed from the patient's blood in this device by means of both diffusion and convection through the membrane and into the countercurrent flowing dialysis solution during hemodialysis. The dialysate exits the devices via a dialysate outlet port.

Indications for Use:
The dialyzer is intended for the treatment of chronic and acute renal failure by hemodialysis.

Technological Characteristics:
The proposed device configurations have the same technological characteristics and are similar in design, function, composition, and operation, to the currently marketed configurations.

Summary of Non-Clinical Tests:
In vitro testing was conducted to compare the performance of the proposed device configurations to the predicate configurations.

In Vitro Performance Testing:
The performance characteristics of the submitted Revaclear 300 and 400 were determined according to requirements of ISO 8637" Cardiovascular implants and extracorporeal systems - Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators".

The following characteristics were determined:

- Clearances of urea, creatinine and vitamin B12
- Flow resistance of blood and dialysate compartments
- Ultrafiltration coefficient

Detailed measurement results are provided in Section 17 of this submission.

Biocompatibility Evaluation:
Biocompatibility of the submitted devices Revaclear 300 and 400 was evaluated according to current ISO 10993-1 and FDA Memorandum G-95-1 the device is classified as external communicating device, body contact with circulating blood and prolonged (>24h to ≤ 30 days) contact duration.

Revaclear 400 was chosen as a master product for testing as it is the biggest product in the product family.

The biological end-points studied for the device were cytotoxicity, sensitization, irritation/ intracutaneous reactivity, systemic toxicity (acute), systemic toxicity (subacute), genotoxicity and hemocompatibility. These endpoints are recommended to be evaluated by the ISO 10993-1 and FDA Memorandum G-95-1.

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In addition, chemical analyses were performed to characterize the materials and to identify and quantify potential leachables as recommended by ISO 10993-1 and ISO 10993-18. According to the results of the biological in vitro and in vivo testing and of the chemical analyses performed in these studies, Revaclear 300 and 400 dialyzers did not induce any adverse biological effects.

Available data covers the requirements according to ISO 10993 and FDA Memorandum G-95-1. Based on chemical and biological test results, Revaclear 300 and 400 is approved for its intended use in haemodialysis for chronic and acute treatment of renal disease.

The complete biological and chemical report is provided in Attachment 4 of the submission.

Mechanical Hemolysis:
Mechanically induced hemolysis was tested in three experiments. In each experiment three filters were tested in parallel, whereas Revaclear 300 and Revaclear 300 filters with alternative materials were compared to Revaclear predicate devices.

Samples were taken every 15 minutes starting at the beginning of recirculation and free hemoglobin (fHb) levels were detected in duplicate according to 405 nm method.

Using the above described conditions for the test set-up no systemic increase in free hemoglobin as marker for hemolysis could be detected for the Revaclear 300 filters compared to the predicate device. These results indicate that the filters are comparable regarding hemolysis.

The complete report is enclosed in Attachment 5 of the submission.

Summary of Clinical Tests:
N/A

Conclusion:
Testing performed on the Gambro Revaclear Dialyzers indicates that they are safe, effective and perform as well as the predicate devices, when used in accordance with the instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2013

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

Re: K130039
Trade/Device Name: Revaclear™ 300 and 400 Dialyzer
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: February 4, 2013
Received: February 5, 2013

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 -S

for

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

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Indications for Use

510(k) Number (if known): K130039

Device Name: Revaclear™ 300 and 400 Dialyzer

Indications for Use:

Revaclear™ 300 and 400 dialyzers are indicated for treatment of chronic and acute renal failure by hemodialysis.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130039