510(k) Summary

MAY 2 7 2005

Submitter: Gambro Renal Products
10810 West Collins Avenue
Lakewood, Colorado 80215

Contact: Thomas Dowell, Project Manager, Regulatory Affairs

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Date prepared: November 19, 2004, revised 4/26/2005

Device name: Gambro Polyflux Capillary Dialyzer labeled for Single and Multiple Use

Common name: Hemodialyzer / Filter

Classification name: High Permeability Hemodialysis System Accessory (876.5860)

Predicate Devices:

Polyflux 14L, 17L, 21L	Hemodialyzer / Filter	K040255 Cleared 5/24/2004
Polyflux 140H, 170H, 210H	Hemodialyzer / Filter	K030592 Cleared 5/23/2003
Polyflux 6LR, 8LR, 10LR	Hemodialyzer / Filter	K023615 Cleared 5/6/2003
Polyflux 6L, 8L, 10 L	Hemodialyzer / Filter	K010985 Cleared 10/10/2001
Polyflux 24S, 24R	Hemodialyzer / Filter	K010667 Cleared 6/4/2001
Polyflux 17R, 21R	Hemodialyzer / Filter	K994390 Cleared 10/26/2000
Polyflux 11S, 14S, 17S, 21S	Hemodialyzer / Filter	K982414 Cleared 3/26/1999

Device Description:

The Gambro Polyflux family Capillary Dialyzers/Filters, labeled for single and multiple use, have the same design, materials, intended use and function as other hemodialyzers / filters currently marketed in the United States.

These devices are intended for use in hemodialysis for the treatment of acute and chronic renal failure. They may also be used in cases of acute fluid overload for the removal of plasma water.

The membrane used in this device is a blend of polyarylethersulfone (PAES), PVP, and Polyamide, which is identical to the membrane used in the Gambro Polyflux H single use hemodialyzers cleared under 510K Notification (K030592) and the Polyflux L dialyzers cleared under 510(k) Notification (K010985).

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 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 capillary dialyzer is intended for use in hemodialysis and associated modalities for the treatment of chronic and acute renal failure.

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.

Summary of Clinical Tests:

Clinical studies demonstrated that the proposed Polyflux Dialyzers / Filters meet the same acceptance criteria as the predicate devices.

Conclusion:

Testing performed on the Gambro Polyflux Dialyzers / Filters 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
9200 Corporate Boulevard
Rockville MD 20850

Mr. Thomas B. Dowell
Regulatory Project Manager
Gambro® Renal Products
10810 W. Collins Avenue
LAKEWOOD CO 80215

MAY 2 7 2005

Re: K043342
Trade/Device Name: Gambro Polyflux Hemodialyzer / Filters
Polyflux H, L, and S Dialyzers (Single Use)
Polyflux R and LR Dialyzers (Multiple Use)
Regulation Number: 21 CFR § 876.5820
21 CFR § 876.5860
Regulation Name: Hemodialysis system and accessories
High permeability hemodialysis system
Regulatory Class: II
Product Code: FJI, KDI, and MSF
Dated: May 3, 2005
Received: May 4, 2005

Dear Mr. Dowell:

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 (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 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 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" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Indications for Use Statement

510(k) number: (if known) K043342

Device Name: **Polyflux Family Hemodialyzer / Filters**

Polyflux H, L, and S Dialyzers (Single Use)
Polyflux R and LR Dialyzers (Multiple Use)

Indications for Use: **The capillary dialyzer is intended for use in hemodialysis and associated modalities for the treatment of chronic and acute renal failure.**

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) ~~AND~~ / OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043342