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510K Notification

Gambro Polyflux 11S, 14S, 17S and 21S

July 7th, 1998

510K(k) SUMMARY

SUBMITTER: Gambro Healthcare
1185 Oak Street
Lakewood, CO 80215
(303) 231-4436

DATE PREPARED: June 1st, 1998

DEVICE NAME: Gambro Polyflux 11S, 14S, 17S, & 21S
Hemodialyzers/filters

CLASSIFICATION NAMES: High Permeability Hemodialyzer / Hemofilter

PREDICATE DEVICE: Cobe Centrysystem 14 PES Hemodialyzer

Device Description:

Gambro Polyflux 11S, 14S, 17S, and 21S, Hemodialyzers/Filters

The Gambro Polyflux 11S, 14S, 17S, & 21S Hemodialyzers/Hemofilters are identical in construction in function to other hemodialyzers/filters currently marketed in the United States. These devices are intended for use in hemodialysis and hemofiltration for the treatment of acute and chronic renal failure and for certain types of intoxications. They may also be used in cases of acute fluid overload for the removal of plasma water. The membrane used in this device is polyarylether sulfone (polyethersulfone) (PES) which is identical to the membrane utilized in the Cobe Centrysystem 14 PES hemodialyzer which has been previously approved for marketing in the United States under a 510K Notification (K95-5592). A copy of this approval letter is included in Part D. of Section XIV of this Notification.

Blood enters a blood inlet port where it is distributed to polyarylethersulfone hollow fibers. Each hollow fiber has an inner diameter of approximately 215 microns (wet hollow fiber internal diameter) and a wall thickness of 50 microns. The number of polyarylethersulfone hollow fibers in each hemodialyzer / hemofilter are 8000 for the 11S, 10000 for the 14S, 10000 for the 17S, and 12500 for the 21S. These dialyzers have effective membrane lengths of either 210mm (11S & 14S) or 250 mm (17S & 21S). The effective membrane surface areas are 1.1 m² for the 11S, 1.4 m² for the 14S, 1.7 m² for the 17S, and 2.1 m² for the 21S. The housing of this hemodialyzer is also made of polycarbonate. The fibers used in this device are identical in design and materials to the previously approved Cobe Centrysystem 14 PES (K95 5592) (please refer to Parts A., B. C. and D. of Section XIV. of this Notification for information on the Cobe Centrysystem 14 PES Hemodialyzer). 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 polyarylethersulfone membrane,

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

Predicate Devices:

The Gambro Polyflux 11S, 14S, 17S, and 21S hemodialyzers/filters are substantially equivalent in construction, design, intended use, function and materials to other high permeability hemodialyzers currently marketed in the United States. Gambro Polyflux 11S, 14S, 17S, and 21S hemodialyzers/filter are substantially equivalent in function, design, composition, materials, and operation, to the Cobe Centrysystem 14 PES hemodialyzer (K95 5592) which is currently in commercial distribution in the United States.

Intended Use:

The Gambro Polyflux 11S, 14S, 17S, and 21S hemodialyzers can be used whenever hemodialysis and hemofiltration is indicated. This can be used for acute or chronic hemodialysis and hemofiltration. In these therapies, monitoring of patient vital signs, the therapy delivery system, heparin administration, and clotting times should be performed under the direction of a physician.

This indication statement is essentially the same as the indication statement for the predicate device.

Technological Characteristics:

Comparing the proposed device to the predicate device, some similarities and differences are noted in the design employed to accomplish the same intended use. Both the proposed and predicate devices use the same polyarylethersulfone, hollow fiber membrane. Both the proposed and predicate devices use polycarbonate for the housing and header material and polyurethane for the membrane potting material. The predicate device is different from the proposed device in that it uses a different membrane surface areas and has different blood side priming volumes and performance parameters (i.e. clearances, etc.).

Summary of Non-Clinical Tests:

In vitro testing was performed on the Gambro Polyflux 11S, 14S, 17S, and 21S hemodialyzers/hemofilter to determine the following: blood side priming volume, dialysate side priming volume, dialysate and blood flow resistance, ultrafiltration coefficient, urea, creatinine, phosphate, and vitamin B12, clearances. The results of these tests confirmed that the proposed device is substantially equivalent to the proposed device for these parameters.

Clinical Test Results:

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Clinical testing was not performed

Conclusions:

Testing performed on the Gambro Polyflux 11S, 14S, 17S, and 21S indicates that they are safe, effective, and perform as well as the predicate device, when used in accordance with the instructions for use.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Jeffrey R. Shideman, Ph.D.
Gambro Healthcare
7307 Gloucester Drive
Edina, MN 55435Re: K982414
Gambro Polyflux 11S, 14S, 17S, and 21S
Hemodialyzers/Hemofilters
Dated: January 31, 1999
Received: February 3, 1999
Regulatory Class: III
21 CFR 876.5860/Procode: 78 KDI

Dear Dr. Shideman:

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

