

K994390  
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OCT 26 2000

510K(k) SUMMARY

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

**DATE PREPARED:** July 17<sup>th</sup>, 2000

**DEVICE NAME:** Gambro Polyflux 17R & 21R Capillary  
Dialyzers/Filters Labeled for Multiple Use

**CLASSIFICATION NAMES:** High Permeability Hemodialyzer / Hemofilters

**PREDICATE DEVICE:** Gambro Polyflux 17S & Gambro 21S  
Hemodialyzers/Filters  
Labeled for Single Use

Device Description:

Gambro Polyflux 17R & 21 R Capillary Dialyzers/Filters Labeled for Multiple Use

The Gambro Polyflux 17R and 21R, Capillary Dialyzers/Filters labeled for multiple use (reuse) are identical in construction in function to Gambro Polyflux 17S and 21S Hemodialyzers / Hemofilters labeled for single use which are currently marketed in the United States and have been previously cleared by the FDA under 510(k) Notification K981414. Only the product designation "R" has been changed from "S" to designate that they are labeled for multiple use (reuse).

These devices are intended for use in hemodialysis for the treatment of acute and chronic renal failure and for certain types of intoxications for both single when reprocessed for reuse for a maximum of 15 reprocessing reuse cycles on the same patient. If reprocessing and reuse is practiced, it is recommended that the reuse be done under the conditions as existed in the in vitro and confirmatory clinical studies undertaken by Gambro and presented in the labeling for this device. It may also be used in cases of acute fluid overload for the removal of plasma water. The membrane used in these devices is polyethersulfone (PES) which is identical to the membrane utilized in the Gambro Polyflux 17S and 21S Hemodialyzers / Hemofilters for labeled for single use which have been previously approved for marketing in the United States under a 510K Notification (K982414). A copy of this approval letter is included in Appendix I of this Notification.

Blood enters a blood inlet port where it is distributed to polyethersulfone 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 polyethersulfone hollow fibers in each hemodialyzer / hemofilter is 10,000 for the Polyflux 17R and 12,500 for the 21R. These dialyzers have an effective membrane length of 250 mm. The effective membrane surface area is 1.7 square meters for the 17R and 2.1 square meters for the

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510K Notification  
Gambro Polyflux 17R Labeled for Multiple Use  
December 2<sup>nd</sup>, 1999

21R. The housing and end caps of these hemodialyzers / hemofilters are made of polycarbonate. The fibers used in the Gambro Polyflux 17R and 21R are identical in design and materials to the previously approved Gambro Polyflux 17S and 21S Hemodialyzers / Hemofilters for labeled for single use (K982414). 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 polyethersulfone membrane, 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 polyethersulfone 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 17R and 21R Capillary Dialyzers / Filters labeled for multiple use (reuse) is identical in design and construction to the currently marketed Gambro Polyflux 17S and 21S, Hemodialyzers / Filters, respectively, labeled for single use which have been approved for marketing / sale in the United States under a 510K Notification (K982414). Both the predicate and the proposed devices, incorporate an identical polyethersulfone membrane and other blood contact materials. They are the same device with the exception of the labeling. The intended use for the proposed and predicate devices is also the same; hemodialyzer/ filter.

**PREDICATE DEVICE**

DEVICE NAMES	Gambro Polyflux 17S & 21S, Hemodialyzers / Filters labeled for Single use
INTENDED USE	Hemodialyzer/Filter
510K NUMBER	K982414
APPROVAL DATE	3/26/99

With respect to performance, these hemodialyzers/filters perform in a manner substantially equivalent to each other. We therefore consider the predicate devices substantially equivalent to existing products in commercial distribution in the United States

**Intended Use:**

*POLYFLUX R is indicated for use in hemodialysis for the treatment of chronic or acute renal failure. The choice of the filter is the responsibility of the physician. Special attention must be paid in connection with pediatric use.*

**CAUTION!** *If POLYFLUX R is reused, the procedure and disinfection specified in the RENATRON INSTRUCTION MANUAL must be followed.*

*The POLYFLUX R may be reprocessed for reuse on the same patient.*

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

**Technological Characteristics:**

Comparing the proposed devices to the predicate devices, they are identical with the exception that one is labeled for single use (Gambro Polyflux 17S & 21S Hemodialyzer/Filters and the other is labeled for multiple use (reuse) (Gambro Polyflux 17R & 21R Hemodialyzer/Filter. Both the proposed and predicate devices use the same polyethersulfone, hollow fiber membrane. Both the proposed and predicate devices use polycarbonate for the housing and header material and polyurethane for the membrane potting material.

**Summary of Non-Clinical Tests:**

In vitro data was collected according to the FDA Guidance for Hemodialyzer Reuse Labeling.

**Clinical Test Results:**

Clinical data was collected according to the FDA Guidance for Hemodialyzer Reuse Labeling.

**Conclusions:**

Testing performed on the Gambro Polyflux 17R and 21R Capillary 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. In vitro and in vivo performance data and directions for reuse have been included in the labeling.

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 26 2000

Jeffrey R. Shideman, Ph.D.  
Gambro Healthcare  
225 Union Boulevard  
Suite 600  
Lakewood, CO 80228Re: K994390  
Multiple Use Labeling for Gambro  
Polyflux 17R and 21R Hemodialyzers  
Dated: July 17, 2000  
Received: July 28, 2000  
Regulatory Class: II  
21 CFR §876.5860/Procode: 78 MSF

Dear Dr. Shideman:

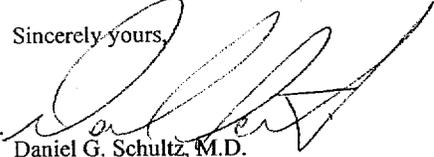
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4639. 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" (21CFR 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,

  
Daniel G. Schultz, M.D.  
Captain, USPHS  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

510 (k) NUMBER (IF KNOWN): K994390

DEVICE NAME: Gambro Polyflux 17R & 21R

**INDICATIONS FOR USE:**

Indications for Use Statement

*POLYFLUX R is indicated for use in hemodialysis for the treatment of chronic or acute renal failure. The choice of the filter is the responsibility of the physician. Special attention must be paid in connection with pediatric use.*

*CAUTION! If POLYFLUX R is reused, the procedure and disinfection specified in the RENATRON INSTRUCTION MANUAL must be followed.*

*The POLYFLUX R may be reprocessed for reuse on the same patient.*

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

*David A. Seymour*  
\_\_\_\_\_  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K994390/5001