2/24/99

510K(k) SUMMARY

SUBMITTER:

Gambro Healthcare
Formerly: Cobe Renal Care, Inc.
1185 Oak Street
Lakewood, CO 80215
(303) 231-4436

DATE PREPARED: **October 15th, 1997**

DEVICE NAME: **Hospal Multiflow 100, Multiflow 100 Kits A0, Multiflow 100 Kits B22**

CLASSIFICATION NAMES: **High Permeability Hemodialyzer**

PREDICATE DEVICE: **Hospal Kit Multiflow 60P**

Device Description:

The Hospal Multiflow 100, Multiflow 100 Kit A0, Multiflow 100 Kit B22 are identical in construction in function to other hemofilters currently marketed in the United States. These devices are intended for use in continuous pump assisted veno-venous hemofiltration and. The membrane used in this device is Acrylonitrile and sodium methallyl sulfonate copolymer (AN69) which is identical to the membrane utilized in the Kit Multiflow 60P which have been previously approved for marketing in the United States under a 510K Notification (K884365).

Blood enters a blood inlet port where it is distributed to Acrylonitrile and sodium methallyl sulfonate copolymer (AN69) hollow fibers. Each hollow fiber has an inner diameter of approximately 240 microns (wet hollow fiber internal diameter) and a wall thickness of 50 microns. There are 6,000 Acrylonitrile and sodium methallyl sulfonate copolymer (AN69) hollow fibers having an effective length of 27 cm. The effective membrane surface area of the Multiflow 100 hemofilter is 0.90 m^2. At either end of the device the hollow fibers are potted in polyurethane to isolate the blood compartment from the filtrate compartment. Each end of the hemofilter is sealed using a silicone O-ring and polycarbonate end cap. The housing of this hemofilter is also made of polycarbonate. The fibers used in this device are identical in design and materials to the previously approved Hospal Kit Multiflow 60P. 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 Acrylonitrile and sodium methallyl sulfonate copolymer (AN69) 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 the Acrylonitrile and sodium methallyl sulfonate copolymer

(AN69) membrane and into the counter current flowing dialysis solution during CVVHD. During CVVH, no dialysis solution is perfused through the filtrate compartment in which case removal of plasma water and uremic toxins is accomplished by means of convection alone. The dialysate exits the devices via a dialysate outlet port. Schematic drawings of the Hospal Multiflow 100, Multiflow 100 Kit A0, and Multiflow 100 Kit B22 are included in this Section.

MULTIFLOW 100 KIT A0, MULTIFLOW 100 KIT B22

- The Multiflow 100 Kit A0 (A0, A0/B and A0/0) and Multiflow 100 Kit B22 (B22, B22/B, & B22/0) are an extracorporeal blood circuit with the Multiflow 100 Hemofilter and are intended to be used with a variety of equipment for pump assisted CVVH, and CVVHD. The Multiflow 100 Kit B22 consists of the Multiflow 100 Hemofilter pre-attached to blood tubing. The Multiflow 100 Kits A0 (A0, A0/B and A0/0) and Multiflow 100 Kits B22 (B22/B22/B/B22/0) can be used for continuous veno-venous hemodialysis (CVVHD), continuous veno-venous hemofiltration (CVVH). These kits are designed to operate with pump-assisted blood circulation. An ultrafiltrate / dialysate collection and measurement set is also included with these kits.

- The component parts of the Multiflow Kits 100 B22/B22/B/B22/0 are:

1. A Multiflow 100 Hemofilter
2. A arterial blood line
3. A venous blood line
4. An ultrafiltrate line
5. A ultrafiltrate/dialysate measuring container (not in the B22/0 Kit)
6. A 5 liter ultrafiltrate/dialysate collection container (included in only the B22Kit)
7. A priming adaptor
8. A reinfusion line

- The component parts of the Multiflow Kits 100 A0, A0/B and A0/0 are:

1. A Multiflow 100 Hemofilter
2. An ultrafiltrate line
3. A ultrafiltrate/dialysate measuring container (included in only the A0 Kit)
4. A 5 liter ultrafiltrate/dialysate collection container (included in only the A0/B Kit)
5. A priming adaptor

Predicate Devices:

The Hospal Multiflow 100 and Multiflow 100 Kits A0 and Multiflow 100 Kits B22 are substantially equivalent in construction, design, intended use, function and materials to other hemofilter kits currently marketed in the United States. The Hospal Multiflow 100 and Multiflow 100 Kits A0 and Multiflow 100 Kits B22 are substantially equivalent in function, design, composition, materials, and operation, to the Hospal Kit Multiflow 60P Kit (K924437) which is currently in commercial distribution in the United States.

Intended Use:

The Hospal Multiflow 100 and Multiflow 100 Kits A0 and Multiflow 100 Kits B22 can be used whenever continuous veno-venous hemofiltration or hemodialysis is indicated. This can be used for acute hemodialysis, 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 utilize the same AN69, hollow fiber membrane manufactured by Hospal Industrie. Both the proposed and predicate devices utilize 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 utilizes a larger membrane surface area and has a slightly larger blood side priming volume.

Summary of Non-Clinical Tests:

In vitro testing was performed on the Multiflow 100 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, inulin, myoglobin, and albumin sieving coefficients. The results of these tests confirmed that the proposed device is substantially equivalent to the proposed device for these parameters.

Clinical Test Results:

Clinical testing was not performed

Conclusions:

Testing performed on the Multiflow 100 and Multiflow 100 A0 and Multiflow 100 B22 Kits indicates that they are safe, effective, and perform as well as the predicate device, 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

FEB 24 1999

Jeffrey R. Shideman, Ph.D.
GAMBRO Healthcare
1185 Oak Street
Lakewood, CO 80215

Re: K980386
Hospal Multiflow 100, Multiflow 100 Kits A0,
and Multiflow 100 Kits B22
Dated: June 8, 1998
Received: June 9, 1998
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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980386

Device Name: ~~Hospal Multiflow 100~~ Multiflow 100 Kits A0 and B22

Indications For Use:

The Hospal Multiflow 100 and Multiflow 100 Kits A0 (A0/B A0 and A0/0) and Multiflow 100 Kits B22 (B22, B22B, & B22/0) can be used whenever continuous arterio-venous or veno-venous hemofiltration, ultrafiltration or hemodialysis is indicated. This can be used for acute hemodialysis, hemofiltration or continuous ultrafiltration. 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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Nathing

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980386

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)