K955487
P1 of 2

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510K Notification
Gambro Polyflux 14, 17 and 21 Hemodialyzers
Supplemental Information: 7/10/96

510K(k) SUMMARY

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

DATE PREPARED: July 10th, 1996

DEVICE NAME: Gambro Polyflux 14, 17, and 21 Hemodialyzers

CLASSIFICATION NAMES: High Permeability Hemodialyzers

PREDICATE DEVICE: Gambro Polyflux 11 Hemodialyzer

Device Description:

The membrane used in these devices is Polyamide which is identical to the polyamide membrane utilized in the Gambro Polyflux 11 dialyzers which have been previously approved for marketing in the United States under a 510K Notification (K933818). This membranes is manufactured by Gambro Dialysatoren of Germany.

Blood enters a blood inlet port where it is distributed to polyamide hollow fibers. Each hollow fiber has an inner diameter of approximately 220 microns and a wall thickness of 50 microns. The effective length of the fibers is 210 mm for the Polyflux 14 and 250 mm for the Polyflux 17 and 21. The fibers used in this device are substantially equivalent in design to the previously approved Gambro Polyflux 11 hemodialyzers. 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 Polyamide membrane, plasma water along with certain lower molecular weight solutes of plasma water pass through the membrane and into the dialysate compartment of the devices. 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 Polyamide membrane into the counter current flowing dialysis solution. The dialysate exits the devices via a dialysate outlet port.

Predicate Devices:

The Gambro Polyflux 14, 17, and 21 hemodialyzers are substantially equivalent in construction, design, intended use, function and materials to other hemodialyzers currently marketed in the United States. The Gambro Polyflux 14, 17, and 21 hemodialyzers are substantially equivalent in function, design, composition, materials, and operation, to the Gambro Polyflux 11 Hemodialyzers (K933818) which are currently in commercial distribution in the United States.

Intended Use:

The Gambro Polyflux 14, 17, and 21 hemodialyzers can be used whenever hemodialysis is indicated. This dialyzer can be used for long term chronic hemodialysis as well as for acute hemodialysis. In hemodialysis therapy, monitoring of patient vital signs, the dialysate 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 Polyamide , hollow fiber membrane manufactured by Gambro Dialysatoren. 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 smaller membrane surface area, and has a smaller blood side priming volume.

Summary of Non-Clinical Tests:

In vitro testing was performed on the Polyflux 14, 17, and 21 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 at varying blood flows and residual blood volume. 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 Gambro Polyflux 14, 17, and 21 hemodialyzers indicates that they are safe, effective, and performs as well as the predicate device, when used in accordance with the instructions for use.