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510K(k) SUMMARY

SUBMITTER: Gambro Healthcare
Formerly: Cobe Renal Care, Inc.
1185 Oak Street
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DATE PREPARED: October 9th, 1996

DEVICE NAME: Cobe Centrysystem 14 PES Gamma

CLASSIFICATION NAMES: High Permeability Hemodialyzer

PREDICATE DEVICE: Fresenius F80 A Hemodialyzer
Gambro HC 14R Hemoconcentrator

Device Description:

The membrane used in this device is polyether sulfone which is substantially equivalent to the polysulfone membrane utilized in the Fresenius F80A dialyzers and the polyether sulfone membrane utilized in the Gambro HC 14 R Hemoconcentrators. Both devices have been previously approved for marketing in the United States under 510K Notifications. The polyether sulfone membrane is manufactured by Gambro.

Blood enters a blood inlet port where it is distributed to polyether sulfone hollow fibers. Each hollow fiber has an inner diameter of approximately 215 microns and a wall thickness of 50 microns. The effective length of the fibers is 267 mm. The fibers used in this device are substantially equivalent in design to the previously approved Gambro HC 14R Hemoconcentrator. 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 Polyether sulfone 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 Polyether sulfone membrane into the counter current flowing dialysis solution. The dialysate exits the devices via a dialysate outlet port.

Predicate Devices:

The Cobe Centrysystem 14 PES Gamma hemodialyzer is substantially equivalent in construction, design, intended use, function and materials to other hemodialyzers currently marketed in the United States. Cobe Centrysystem 14 PES Gamma hemodialyzer is substantially equivalent in function, design, composition, materials, and operation, to the Fresenius F80A hemodialyzer and Gambro HC 14R Hemoconcentrator which are currently in commercial distribution in the United States.

Intended Use:

The Centrysystem 14 PES Gamma 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 Polyether sulfone, hollow fiber membrane manufactured by Gambro. 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 different membrane surface area, is gamma sterilized rather than ethylene oxide sterilized.

Summary of Non-Clinical Tests:

In vitro testing was performed on the Centrysystem 14 PES Gamma 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 performed utilizing 24 Cobe Centrysystem 14 PES Hemodialyzers in six patients. Parameters studied during these clinical tests included pressure drops across the blood compartment and dialysate compartment, blood flows, transmembrane pressures, ultrafiltration rates, urea clearances, creatinine clearances, phosphate clearances, beta 2 microglobulin clearances, residual blood volumes and handling and safety evaluations.

It can be concluded from the results of the investigation that the Cobe Centrysystem 14 PES Gamma Hemodialyzer fulfills the performance criteria stated by Gambro.

Conclusions:

Testing performed on the Cobe Centrysystem 14 PES Gamma indicates that it is safe, effective, and performs as well as the predicate device, when used in accordance with the instructions for use.