JUN 9 - 2005

510(k) Summary

Submitter

Nephros, Inc.
3960 Broadway
New York, NY 10032
USA

Contact:

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Date summary was prepared:

3/8/05

Name(s) of the device

OLpūr™ HD 190 Dialyzer

Identification of predicate device(s)

The OLpūr HD 190 Dialyzer is substantially equivalent to the following devices:

Gambro Polyflux 21S Dialyzer, 510(k) # K982414

Asahi APS 21R Dialyzer, 510(k) # K001250

Description of the device

The OLpūr™ HD 190 Dialyzer is a sterile, non-pyrogenic, single use, high permeability hemodialyzer intended to be used in providing hemodialysis and hemodiafiltration to patients with acute or chronic renal failure. This dialyzer is designed for use only with UF controlled dialysis equipment and is compatible with all models of this generic type of equipment currently in use in the US. The individual dialyzers are packaged in a pouch constructed of Polyamide/Polyethylene film and a Tyvek® backing. The individually packaged dialyzers are packaged twelve to a carton and thirty-six to a shipping container.

The dialyzer membranes used in this device consist of polyethersulfone (PES). The hollow fiber membranes are potted in a polyurethane compound at each end within a polycarbonate dialyzer casing to form a tubesheet. A polycarbonate blood inlet header attached to the end of the casing directs the incoming blood into the hollow fibers. The blood then flows through the inside of the

hollow fibers and exits out through the polycarbonate blood outlet header attached to the other end of the casing. Inlet and outlet dialysate (Hansen) ports on the dialyzer casing allow for the flow of dialysate around the outside of the hollow fibers counter-current to the blood flow. Uremic toxins and excess plasma water are removed from the blood across the semi-permeable hollow fibers. A combination of diffusion, due to the concentration differences between the blood and dialysate, and convection, due to the transmembrane pressure differential across the hollow fibers, leads to the toxin removal. The spent dialysate exits the device via the dialysate outlet port.

As received by the customer, the dialyzer's blood and dialysate ports are covered with polyethylene sterility caps. Silicone o-rings are included in the connections between the headers and the dialyzer tubesheet at each end of the dialyzer to provide a fluid-tight seal between the headers and the tubesheet.

Intended Use

The OLpūr™ HD 190 Dialyzer is indicated for hemodialysis and hemodiafiltration of patients with acute or chronic renal failure.

Comparison of device characteristics to predicate

The OLpūr HD 190 Dialyzer is substantially equivalent to the Gambro Polyflux 21S, in that they are both sterile, single use, high permeability hemodialyzers with the same intended use, of similar construction, made with the same type of membrane material and comparable in regard to their performance characteristics.

The OLpūr HD 190 Dialyzer is also substantially equivalent to the Asahi APS 21R in that they are both sterile, high permeability hemodialyzers with similar intended use, of similar construction and materials, made with the same type of membrane material and comparable in regard to their performance characteristics.

Nonclinical testing

OLpūr HD 190 Dialyzer was subjected to biocompatibility, sterility, pyrogenicity, shelf life, and *in vitro* performance testing to demonstrate its equivalence to the predicate devices. All of the testing supported the substantial equivalence by the similarity of the test results. Both the subject devices and the predicate devices are effective as High Flux Hollow Fiber Hemodialyzers. Based on this data it was concluded that OLpūr HD 190 Dialyzer is substantially equivalent to the Gambro Polyflux 21S Dialyzer and the Asahi APS 21R Dialyzer,

Conclusion

Based on the descriptive information and performance data provided in this premarket notification, it is concluded that the OLpūr HD 190 Dialyzer is substantially equivalent to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 9 - 2005

Ms. Nadia Greenidge
Manager QA/RA
Nephros, Inc.
3960 Broadway
NEW YORK NY 10032

Re: K050603
Trade/Device Name: Nephrol OLpūr™ HD 190 Dialyzer
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: May 26, 2005
Received: May 27, 2005

Dear Ms. Greenidge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K050603

Device Name: OLpūr™ HD 190 Dialyzer

Indications For Use:

The OLpūr™ HD 190 Dialyzer is indicated for hemodialysis and hemodiafiltration of patients with acute or chronic renal failure.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin M Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050603