JUL 2 3 2004

510 (K) SUMMARY

APS Series Dialyzers

Manufacturer:

Asahi Medical Company, Ltd.
9-1, Kanda Mitoshirocho
Chiyoda-ku, Tokyo 101-8482
Japan

Date summary was prepared: June 24, 2004

Name(s) of the device: Asahi APS Series Dialyzers

Identification of predicate device(s): Asahi APS Series Dialyzers

Description of the device:

The line of Asahi Polysulfone (APS) Series Dialyzers is a family of high permeability hollow fiber dialyzers intended for the treatment of patients with acute or chronic renal failure. The Asahi APS Series Dialyzers are designed for both single use or for reuse with a maximum of 15 reprocessing reuse cycles per patient. They are constructed of reusable, hollow fiber (polysulfone) membranes, housed within a plastic casing of styrene butadiene block polymer and are gamma sterilized prior to shipment.

The Asahi APS Series Dialyzers are offered for sale in both a "wet" and a "dry" model. The wet and dry dialyzers are identical to each other except that the wet models filled at the factory with a fluid to facilitate priming by the user and the dry models are not filled. The use of a wet or dry dialyzer is a matter of user preference.

Modifications made to the Asahi APS Series Dialyzers subject of this 510(k) include (1) labeling revised to provide additional information concerning pre-cleaning; (2) modification of the dialyzer housing to diffuse the flow water used in pre-cleaning; and, (3) modification of the shipping carton partition materials and mold.

Intended Use:

The line of APS Series Dialyzers is a family of high permeability hollow fiber dialyzers intended for the treatment of patient with acute or chronic renal failure. The APS Series Dialyzers are intended for both single use or for reuse with a maximum of 15 reprocessing reuse cycles per patient. This is the same intended use as the predicate device - APS Series Dialyzers cleared under K001250.

Evaluation of Design Modifications

As the basis for Asahi Medical's device evaluation studies and overall process for managing medical device risk, the company has performed a risk analysis using procedures based on ISO 14971 (2000) *Medical Devices – Application of Risk Management to Medical Devices*. The risk analysis method used to assess the impact of the modification was Failure Modes and Effects Analysis (FMEA). Design verification tests based on the result of risk analysis were performed to verify those modifications. All test results meet the acceptance criteria, and proved that those modifications to be appropriate.

Conclusion:

Asahi Medical made three modifications to the original APS Series Dialyzers cleared under K001250. All design verification tests based on the result of risk analysis proved that modified APS Series Dialyzers are substantially equivalent in intended use, design, principle of operation/technology, materials, specifications and performance to the original APS Series Dialyzers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2004

Asahi Medical Company, Ltd.
c/o Mr. David L. West, Ph.D.
Vice President
Quintiles Consulting
1801 Rockville Pike
ROCKVILLE MD 20852

Re: K041726
Trade/Device Name: High Flux Hemodialysis Membrane Dialyzer or High Flux Hollow Fiber Dialyzer, Models APS-R, -M, -S, -E, and –EX
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: June 25, 2004
Received: June 25, 2004

Dear Dr. West:

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 (PMA), it may be subject to 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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 STATEMENT

510(k) Number:

Device Name: Asahi APS Series Dialyzers

Indications for Use:

A. APS Series Dialyzers are intended for use for hemodialysis treatment of patients who have chronic renal failure or acute renal failure.

B. APS Series Dialyzers must be used in accordance with the instructions for a physician familiar with hemodialysis and familiar with the conditions of the patient.

C. APS Series Dialyzers have been tested *in vitro* and in confirmatory clinical studies under single or initial use and under reprocessing and reuse conditions for up to 15 reuse cycles. Based on the results from these evaluations, Asahi APS Series Dialyzers may be reprocessed for reuse 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 as recommended immediately below. It is noted that the Asahi APS Series Dialyzers have not been tested for reuse when reprocessed with agents and/or processes other than these, and the performance of the dialyzers under other conditions are not known and cannot be recommended. Accordingly:

(1) The reprocessed dialyzer may be used only if the residual Total Cell Volume (TCV) is at least 80% of the original TCV and if such dialyzer otherwise meets the acceptance criteria of these instruction for use and the instruction of the reprocessing system utilized. Furthermore, the policies, instructions, and criteria of the institution for reuse (e.g., concerning dialyzer performance, residual blood, and/or dialyzer leakage or damage) should be followed.

(2) The reprocessing agent may be either (1) 4% formaldehyde (also known as formalin) in conjunction with the Seratronics Dialyzer Reprocessing Systems for Dialyzer Reprocessing and Preparation (DRS4™ and DPS4™), manufactured by Seratronics, Inc., or (2) Renalin ® (peroxyacetic acid) in conjunction with the Renatron ® Dialyzer Reprocessing System (RS 8300), manufactured by Renal Systems, Inc.

(3) The instructions provided by the manufacturer of the chosen reprocessing agent must be followed in reprocessing the dialyzer.

(4) The reprocessed dialyzer may be used only on dialysis systems equipped with volumetric ultrafiltration controllers.

Concurrence of CDRH, Office of Device Evaluation (ODE)

☑ Prescription Use (per 21 CFR 801.109)

☐ Over-the Counter Use

David G. Legleiter

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041726