K970650

SEP 30 1997

Submitter

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Date summary was prepared

February 3, 1997

Name of the device

Asahi AM-R Series Dialyzers

Identification of predicate device

Asahi AM-Series Dialyzers

Description of the device

The AM-R Series Dialyzers are a family of hemodialyzers developed to provide safe and effective hemodialysis over ranges of dialyzer patient treatment requirements. The performance of these dialyzers, when new for single or initial (first) use and when reprocessed for reuse, have been documented through laboratory (*in vitro*) testing and confirmatory clinical testing. Asahi AM-R Series Dialyzers are constructed of hollow fiber membranes of cuprammonium rayon housed within a plastic casing of styrene butadiene block polymer. Asahi AM-R Series Dialyzers are sterilized before shipment by gamma radiation (γ-rays). The dialyzer is no longer sterile after its sterile package is opened for the initial (first) use.

Intended Use

Asahi AM-R Series Dialyzers are intended for use for hemodialysis treatment of patients who have chronic renal failure or acute renal failure.

K970650

Asahi AM-R Series Dialyzers have been tested *in vitro* and in confirmatory clinical studies under reprocessing and reuse conditions for up to 15 reuse cycles. Based on the results from these evaluations, Asahi AM-R 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 AM-R 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 the instructions for use and the instructions 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® in conjunction with the Renatron® Dialyzer Reprocessing System, 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.

Comparison of device characteristics to predicate

The design, materials of fabrication, and manufacturing of the Asahi AM-R Series Dialyzers remain unchanged from the Asahi AM-Series Dialyzers cleared by FDA for marketing in the U.S. under K892374 and K892375. Therefore, from the perspective of technological characteristics, the AM-R Series Dialyzers under this 510(k) are identical to the predicate device under K892374 and K892375.

Non clinical testing

In accordance with FDA's May 23, 1996, letter and its accompanying *Guidance for Hemodialyzer Reuse Labeling*, the performance of selected models of the family of AM-R Series Dialyzers have been evaluated under reuse conditions. The family of dialyzers, as it will be constituted under this 510(k) are all conventional hemodialysis membranes. Accordingly, the following nonclinical testing has been conducted for dialyzers reprocessed with formalin and Renalin®, respectively:

(1) The largest model (AM-R-90U) has been subjected to the reprocessing agents and/or processes for 15 cycles and subsequently tested for biocompatibility. The biocompatibility tests comprised: cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), genotoxicity, hemocompatibility, and pyrogenicity.

(2) The smallest model (AM-R-50M) and the largest model (AM-R-90U) have been tested *in vitro* under initial use and reprocessed/reused conditions for 15 cycles using out-dated human blood from a blood bank to produce *in vitro* measurements of ultrafiltration coefficient (K_{UF}) and clearances for urea, creatinine, and vitamin B_{12}. Reflecting the dominant use pattern in modern hemodialysis facilities, the *in vitro* performance testing was performed using dialysis machines (COBE Centry III) equipped with volumetric ultrafiltration controllers. Also to evaluate the effects of reprocessing, widely utilized reprocessing agents formaldehyde (also known as

formalin) and Renalin® and associated automated reprocessing systems (Seratronics machine and Renatron® machine, respectively) were utilized.

Clinical testing

In accordance with FDA's May 23, 1996, letter and its accompanying *Guidance for Hemodialyzer Reuse Labeling*, the performance of selected models of the family of AM-R Series Dialyzers have been evaluated under reuse conditions. The family of dialyzers, as it will be constituted under this 510(k) are all conventional hemodialysis membranes. Accordingly, the largest model (AM-R-90U) has been tested in confirmatory clinical studies under initial use and reprocessed/reused conditions for up to 15 reuse cycles to produce *in vivo* measurements of ultrafiltration coefficient (K_{UF}) and removal rates for urea, creatinine, and albumin. To evaluate the effects of reprocessing, widely utilized reprocessing agents formaldehyde (also known as formalin) and Renalin® and associated automated reprocessing systems (Seratronics DRS4™ and DPS4™ machines and Renatron® machine, respectively) were utilized.

Specifically, two clinical sites were chosen to study the effects of reprocessing the dialyzers with the two chosen reprocessing agents and/or processes. The reprocessing was performed in accordance with the instructions of the manufacturer of the reprocessing machines used at the respective institutions. The clinical study protocol was identical for both sites, although dialysis sessions were conducted and patients were managed in accordance with established dialysis practices for the respective institutions.

The study was a prospective study. The initial dialysis procedures served as the baselines for comparison for the subsequent dialysis procedures performed with the reprocessed devices. The study continued at each site until a minimum of 12 patients were enrolled at the site, of which a minimum of 50% reused the dialyzer 15 times. The main inclusion criteria were patients who receive chronic dialysis and who are stable on thrice weekly dialysis.

Conclusion

The design, materials of fabrication, and manufacturing of the Asahi AM-R Series Dialyzers remain unchanged from the Asahi AM-Series Dialyzers cleared by FDA for marketing in the U.S. under K892374 and K892375. Therefore, from the perspective of technological

characteristics, the AM-R Series Dialyzers under this 510(k) are identical, hence, substantially equivalent to the same device under K892374 and K892375.

The performance characteristics of the AM-R Series Dialyzers after reprocessing for reuse, as reflected in the biocompatibility testing, *in vitro* performance testing, and confirmatory clinical testing, are fully comparable to their conventional hemodialysis performance characteristics for single or initial (first) use. The single or initial (first) use, as well as reuse, performance characteristics will be included in device labeling, providing clinical users accurate information on the comparable performance of these conventional hemodialysis membranes. Therefore, from the perspective of performance characteristics, the AM-R Series Dialyzers under this 510(k) are substantially equivalent to the same device under K892374 and K892375.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 1997

Asahi Medical Co., Ltd.
c/o David L. West, Ph.D.
Senior Technical Advisor
Quintiles Medical Technology Consultants
15825 Shady Grove Road, Suite 90
Rockville, Maryland 20850

Re: K970650
Asahi AM-R Series Dialyzers - Multiple Use Labeling
Dated: July 22, 1997
Received: July 22, 1997
Regulatory class: II
21 CFR §876.5820/Product code: 78 MSE

Dear Dr. West:

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 requirement, 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/dsmamain.html".

Sincerely yours,

William Yin

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

K970650

Page 1 of 2

510(k) Number

None assigned as of this time

Device Name

Asahi AM-R Series Dialyzers

Indications for Use

Asahi AM-R Series Dialyzers are intended for use for hemodialysis treatment of patients who have chronic renal failure or acute renal failure.

Asahi AM-R Series Dialyzers have been tested *in vitro* and in confirmatory clinical studies under reprocessing and reuse conditions for up to 15 reuse cycles. Based on the results from these evaluations, Asahi AM-R 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 AM-R 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:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

☑ Prescription Use (per 21 CFR 801.109)

☐ Over-the Counter Use

Robert R Rathing
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970650

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