

510(k) SUMMARY

K991512
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JUL 29 1999

Asahi AM-R Series Dialyzers

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

Date summary was prepared: April 2, 1999

Name(s) of the device: Asahi AM-R Series Dialyzers

Identification of predicate device(s): Asahi AM-R Series Dialyzers

Description of the device:

Asahi AM-R Series Dialyzers cleared under 510(k) K970650 are designed as reusable, hollow fiber (cuprammonium rayon) membranes which are housed within a plastic casing of styrene butadiene block polymer.

Intended Use:

The AM-R Series Dialyzers are indicated for use in hemodialysis treatment of patients who have chronic renal failure or acute renal failure. Asahi AM-R Dialyzers may be reprocessed for reuse on the same patient.

Comparison To Predicate:

The previously cleared Asahi AM-R Series Dialyzers are being modified to update the dialyzer casings. No other changes to the dialyzers are being made.

Conclusion:

Revisions to the casing dimensions for the AM-R Series dialyzers are demonstrated to have an insignificant impact on the performance of the dialyzers. The indications for use remains unchanged and no new issues of safety or effectiveness are expected to be raised as a consequence of this modification. Therefore the modified AM-R series dialyzers are considered substantially equivalent to the original AM-R series dialyzers.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 1999

Asahi Medical Company, Ltd.
c/o David L. West, Ph.D.
Vice President
Quintiles Consulting
15825 Shady Grove Road, Suite 130
Rockville, MD 20850-4008

Re: K991512
Asahi AM-R Series of Dialyzers
Dated: April 29, 1999
Received: April 30, 1999
Regulatory Class: II
21 CFR §876.5820/Procode: 78 FJI

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 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). 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 requirements, 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/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

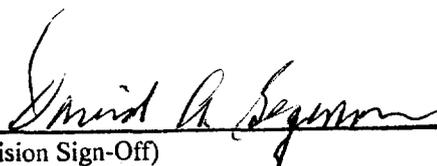
510(k) Number: None assigned as of this time

Device Name: Asahi AM-R Series Dialyzers

Indications for Use: The AM-R Series Dialyzers are indicated for use in hemodialysis treatment of patients who have chronic renal failure or acute renal failure. Asahi AM-R Dialyzers may be reprocessed for reuse on the same patient.

Concurrence of CDRH, Office of Device Evaluation (ODE)

- Prescription Use (per 21 CFR 801.109)
- Over-the Counter Use


David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991512