K013418

**Summary for Public Disclosure**

JUL 9 2002

**SUBMITTER**

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

Tel: 81-3-3259-5880
Fax: 81-3-3259-5899

**DATE SUMMARY WAS PREPARED**

July 8,2001

**NAME OF DEVICE**

Asahi AM-BIO Extended Range Series Dialyzers (AM-BIO-HX series)

**IDENTIFICATION OF PREDICATE DEVICES**

Asahi AM-BIO Series Dialyzers (K983720)
Asahi APS Series Dialyzer (K001250)
Fresenius Hemoflow (K892262)

**DESCRIPTION OF THE DEVICE**

The line of Asahi AM-BIO Extended Range Series Dialyzers (AM-BIO-HX series) is a family of hemodialysis membranes, or hollow fiber dialyzers, developed to provide safe and effective hemodialysis over ranges of dialyzer patient treatment requirements. The device is intended for use in patients who have chronic renal failure or acute renal failure, for only single use.

The membrane fibers are made of modified cellulose (i.e., alkyl ether polymer grafted cellulose), derived from cuprammonium rayon. The cuprammonium rayon is manufactured to have a thin layer of modified cellulose exposed to blood contact surfaces. The modification to the cellulose yields the fiber more compatible to the patient's blood, manifested through lower complement activation ($C3_a$ and $C5_a$) when compared to regular cellulose membrane dialyzers.

The membranes are housed within a plastic casing of styrene butadiene block polymer. Non-removable casing end caps are also made of styrene butadiene block polymer. The potting material (sealant) is polyurethane and the port caps (stoppers) are made of hydrogenated styrene butadiene block polymer. Like the AM-BIO Series Dialyzers, the AM-BIO Extended Range Series Dialyzers will be offered for sale in both a "wet" model and a "dry" model. The wet and dry dialyzers are identical to each other except that the wet models are 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. The fluid in wet dialyzers is made of water containing 600 ppm sodium pyrosulfite and 300 ppm sodium carbonate. Asahi AM-BIO Extended Range Series Dialyzers are sterilized by gamma radiation before shipment.

**INTENDED USE**

The indications for use for the Asahi AM-BIO Extended Range Series Dialyzer is as follows:

a. Asahi AM-BIO Extended Range (AM-BIO-HX series) Dialyzers are intended for use for hemodialysis treatment of patients who have chronic renal failure or acute renal failure.

b. Asahi AM-BIO Extended Range (AM-BIO-HX series) Dialyzers must be used in accordance with the instructions of a physician familiar with hemodialysis and familiar with the conditions of the patient.

c. Asahi AM-BIO Extended Range (AM-BIO-HX series) Dialyzers are intended *for single use only*.

d. Asahi AM-BIO Extended Range (AM-BIO-HX series) Dialyzers are designed only to be used only on dialysis systems equipped with volumetric ultrafiltration controllers.

e. The expiration date of ASAHI AM-BIO Extended Range (AM-BIO-HX series) Dialyzers is 3 years from the sterilization date. The user must use the dialyzers before the expiration date.

**Comparison of Device Characteristics to Predicates**

The indications for use, design, and manufacturing of the Asahi AM-BIO Extended Range Series Dialyzers are the same as a predicate device, the AM-BIO Series Dialyzers. The AM-BIO Extended Range Series Dialyzers have the same materials and construction as the AM-BIO Series Dialyzers, but with extended range of performance specifications to accommodate a more diverse patient population. The intended changes in performance specifications are achieved by changing the pore size of the dialyzer fibers. Note, the AM-BIO Extended Range Series Dialyzers are labeled for only single use.

**Non-clinical Testing**

*In-vitro* testing of the AM-BIO Extended Range Series Dialyzers includes the following:

- Permeability – saline
- Permeability – bovine plasma
- Urea clearance rate
- Creatinine clearance rate
- Phosphate clearance rate

- $B_{12}$ clearance rate

Additionally, the following testing supports the biocompatibility of the AM-BIO Extended Range Series Dialyzers:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Systemic Toxicity (Acute)
- Genotoxicity:
- Hemocompatibility
- Pyrogenicity

## CONCLUSIONS

The indications for use (other than regarding single use), design, and manufacturing of the Asahi AM-BIO Extended Range Series Dialyzers (AM-BIO-HX series) are the same as, and therefore substantially equivalent to, the predicate Asahi AM-BIO Series Dialyzers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 2002

Asahi Medical Company, Ltd.
c/o David L. West, Ph.D.
Vice President, Medical Device
Development
Quintiles Consulting
1801 Rockville Pike, Suite 300
ROCKVILLE MD 20852

Re: K013418
Trade/Device Name: AM-BIO Extended Range Series Dialyzers (HX Series)
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: April 10, 2002
Received: April 10, 2002

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 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:

| | |
|---|---|
| 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" (21 CFR Part 807.97). 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 (if known): _____

Device Name: **Asahi AM-BIO Extended Range Series Dialyzers (AM-BIO-HX series)**

Indications For Use:

a. Asahi AM-BIO Extended Range (AM-BIO-HX series) Dialyzers are intended for use for hemodialysis treatment of patients who have chronic renal failure or acute renal failure.

b. Asahi AM-BIO Extended Range (AM-BIO-HX series) Dialyzers must be used in accordance with the instructions of a physician familiar with hemodialysis and familiar with the conditions of the patient.

c. Asahi AM-BIO Extended Range (AM-BIO-HX series) Dialyzers are intended *for single use only*.

d. Asahi AM-BIO Extended Range (AM-BIO-HX series) Dialyzers are designed only to be used only on dialysis systems equipped with volumetric ultrafiltration controllers.

e. The expiration date of ASAHI AM-BIO Extended Range (AM-BIO-HX series) Dialyzers is 3 years from the sterilization date. The user must use the dialyzers before the expiration date.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Prescription Use* ✓ (Optional Format 3-10-98)

David G. Seymour

**(Division Sign-Off)**
**Division of Reproductive, Abdominal, and Radiological Devices**
**510(k) Number** K013418