K992563
p. 1/3

JAN 1 8 2000

510(k) Summary of Safety and Effectiveness

[As Required by 21 CFR 807.92(c)]

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92(a).

Submitter information.

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Contact person: Lars-Olof Sandberg
Regulatory Affairs Manager

Date Summary Prepared: 990726

Device identification.

Trade/Proprietary name: A-22 Hemodialyzer

Common name: Hemodialyzer

Classification name: High permeability dialyzer per 21 CFR §867.5860

Substantially Equivalent legally marketed device:

Company	Device	510(k) number	Date cleared
Althin Medical Inc	Altra Nova 200 Hemodialyzer	K926379	02/23/95

The A-22 Hemodialyzer is substantially equivalent to other predicate devices currently in commercial distribution in terms of their intended use. The fundamental technical characteristics are similar to those of the predicate device and are listed on the predicate device comparison table provided in this notification.

Device description.
The A-22 Hemodialyzer is a high permeability hemodialyzer that is used as an artificial kidney in a hemodialysis system to treat patients with acute or chronic renal failure. The blood from a patient flows through the arterial tubing of the extracorporeal blood circuit to the blood compartment of the hemodialyzer, then returns through the venous tubing of the extracorporeal blood system to the patient. The hemodialyzer has semipermeable hollow fibers which divide the device into two compartments. When the blood passes through the hollow fibers, water and toxic waste products from the blood pass through the semipermeable membrane into the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the hemodialyzer.

A high permeability hemodialyzer has a semipermeable membrane that is more permeable to water than that of the conventional dialyzer. This device must be used in conjunction with a controlled dialysate delivery system that incorporates an ultrafiltration controller to prevent excessive loss of water from the patient's blood. This highly permeable, semipermeable membrane may also permit greater loss of high molecular weight substances from the blood, compared with the conventional hemodialyzer.

Each A-22 Hemodialyzer is packaged in a plastic bag and 20 hemodialyzers are packed in a cardboard box.

It is sterilized by gamma radiation and intended, and labeled, for single use only.

Intended use of the device.
Hemodialysis with Althin capillary dialyzers are indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate.

Comparison of technical characteristics
The Althin A-22 Hemodialyzer operates using the same hollow fiber technology as the legally marketed predicate device. Apart from differences in ultrafiltration coefficient and clearance, both the subject and predicate devices are used as comparable artificial kidneys in a hemodialysis system to treat patients with acute or chronic renal failure.

Functional testing.
Functional testing has been conducted to evaluate the functional performance of the A-22 Hemodialyzer. Testing was based on the specification cleared for the predicate device and test results showed significant equivalence. Moreover, the results of the functional testing attest that the A-22 Hemodialyzer conforms to its specifications and has demonstrated that it is suitable for its intended use.

Additionally, biocompatibility testing was performed on the finished sterile device in accordance with ISO10993. Test results showed that the A-22 Hemodialyzer passed the panel of tests indicated for a hemodialyzer device.

Conclusions.

The information included in this submission demonstrate that the A-22 Hemodialyzer is similar in design, materials, intended uses, indications and contraindications to the previously concurred Altra Nova 200 Hemodialyzer. Therefore, based on the information provided in this 510(k) Notification, the A-22 Hemodialyzer is considered substantially equivalent to the Altra Nova 200 Hemodialyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2000

Mr. Lars-Olof Sandberg
Regulatory Affairs Manager
Althin Medical AB
Box 39
Fridhemsvägen 15
S-372 21 Ronneby
SWEDEN

Re: K992563
A-22 Hemodialyzer
Dated: July 30, 1999
Received: August 2, 1999
Regulatory Class: III
21 CFR §876.5860/Procode: 78 KDI

Dear Mr. Sandberg:

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.

510(k) number (if known):

Device name: Althin Medical AB A-22 Hemodialyzer

Indications for use: Hemodialysis with Althin capillary dialyzers are indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ OR Over-The-Counter Use _____
(Per CFR 801.109)

(Optional format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992563