

JUL 23 1998

K970679

**Altra Flux® 200 Hemodialyzer with Multiple Use Labeling**

**510(k) Summary of Safety and Effectiveness**

(in accordance with the requirements of SMDA 1990 and 21 CFR 807.92)

The assigned 510(k) number for the Altra Flux® 200 Hemodialyzer with multiple use labeling is: K970679.

**Applicant Information:**

Date Prepared: March 10, 1997  
Name: Althin Medical, Inc.  
Address: 14620 N.W. 60th Ave.  
Miami Lakes, FL 33014-9308  
Contact Person: Mary Lane  
Phone Number: (305) 825-5368  
Fax Number: (305) 825-5322

**Device Information:**

Trade Name: Altra Flux® 200 Hemodialyzer  
Common Name: high permeability hemodialyzer or artificial kidney  
Classification Name: Dialyzer, High Permeability with or without Sealed  
Dialysate System (21 CFR 876.5860) Product Code - 78  
KDI

**Equivalent Device:**

Altra Flux® 200 Hemodialyzer (single use device) cleared for marketing via  
Premarket Notification 510(k) number K926373/B.

**Device Description:**

The Altra Flux® 200 multiple use hemodialyzer is the Altra Flux® 200 single use device with reuse labeling. Like the Altra Flux® 200 single use device, it 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.

**Intended Use:**

Hemodialysis is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. The multiple use device can be reused on the same patient.

**Comparison to Predicate Device:**

The Altra Flux<sup>®</sup> 200 Hemodialyzer with multiple use (reuse) labeling is identical to the currently marketed Altra Flux<sup>®</sup> 200 single use device. The product drawings, material list, chemical structure, production process flow for the membrane or dialyzer, and physical characteristics of the Altra Flux<sup>®</sup> 200 reusable hemodialyzer is identical to the currently marketed Altra Flux<sup>®</sup> 200 single use hemodialyzer which received marketing clearance via the original 510(k) Premarket Notification K926373/B, dated February 13, 1995.

The only difference between the two products is that the multiple use device has been validated for multiple uses. Reprocessing between uses was performed according to the Renatron<sup>®</sup> operator's manual. Testing performed on reprocessed devices demonstrate that the Altra Nova<sup>®</sup> 200 multiple use hemodialyzer is as safe and effective as the currently marketed Altra Nova<sup>®</sup> 200 single use hemodialyzer.



JUL 23 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Mr. Gordon Robertson  
Director, Regulatory Affairs  
Althim Medical, Inc.  
14620 N.W. 60<sup>th</sup> Avenue  
Miami Lakes, FL 33014Re: K970679  
Multiple Use Labeling for the Altra Flux® 200  
Hemodialyzer  
Dated: April 22, 1998  
Received: April 24, 1998  
Regulatory Class: III  
21 CFR 876.5860/Procode: 78 MSF

Dear Mr. Robertson:

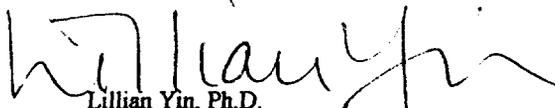
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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,



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

INDICATIONS FOR USE

510(k) Number is if known:

Device Name:

Altra Flux® 200 Hemodialyzer

Indications for Use:

Altra Flux® 200 Hemodialyzers are intended for acute or chronic Hemodialysis.

Hemodialysis is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate.

The Altra Flux 200 Hemodialyzer is indicated for single use or multiple use with the same patient.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(per 21 CFR 801.109)

OR

Over-The-Counter Use

Dale R. Anthony  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K970679