MAY 21 1997

510(k) SUMMARY

Date:

December 4, 1996

Name:

Althin Medical Inc.

Drake Willock® dialysis equipment

Address:

13520 S.E. Pheasant Court
Portland, Oregon 97222-1298

Phone Number: 503-659-3355

Fax Number: 503-652-0225

Contact person: Thomas D. Kelly

Trade Names:

Drake Willock® System 1000® Dialysate Delivery System with AutoStart Disinfection Option

AltraTouch™ 1000 Dialysate Delivery System with AutoStart Disinfection Option

Common Name:

Dialysate Delivery System

Classification Name:

Hemodialysis System and accessories, Class III Device.

Product code:

78KDI

Equivalence Information / Comparison to Predicate Device:

The AutoStart feature is a modification to predicate System 1000® and AltraTouch™ 1000 Dialysate Delivery Systems [510(k) numbers K910215 and K954987.] The System 1000® and AltraTouch™ 1000 single patient hemodialysis delivery systems with the Auto Start option are built with the same fluid path and hardware components as the predicate System 1000® and AltraTouch™ 1000 single patient hemodialysis delivery systems. The only difference is a software change to delay the start of heat clean or fluid path rinse. The machine and patient safety systems are the same as the predicate devices. ★

Althin Medical, Inc. believes that the design and testing of this modified System 1000®/ AltraTouch™1000 Dialysate Delivery System demonstrates that it is safe and effective.

Pages of this 510(k) that refer to the new AutoStart option are marked with a star (★) in the right hand margin.

Device Description:

The Drake Willock® System 1000® Single Patient Dialysate Delivery System is a dialysate proportioning system for hemodialysis. The system fulfills the following functions:

- Mixes concentrate with water in the appropriate proportions to produce dialysate
- Delivers dialysate at the appropriate temperature and ionic concentration to the dialyzer,
- Removes the appropriate amount of liquid from the patient's blood
- Along with the dialyzer and blood pump acts as a total artificial kidney.

The following option is the subject of this submission that will be implemented with FDA approval.

The fundamental modification is to provide the patient care provider with a means to delay the start of fluid path rinse or heat clean up to 3 calendar days. ★

Intended Use:

Intended use of the System 1000® and AltraTouch™ 1000 single patient hemodialysis delivery systems

The intended use of the device is to provide hemodialysis treatments in the acute and chronic setting including high flux hemodialysis.

- The device is intended to be used by trained operators when prescribed by a physician.
- The device is intended to be used in conjunction with a hollow fiber or parallel plate dialyzer.

Intended use System 1000® and AltraTouch™ 1000 single patient hemodialysis delivery systems with the Auto Start option ★

The intended use of the device is to provide hemodialysis treatments in the acute and chronic setting including high flux hemodialysis.

- The device is intended to be used by trained operators when prescribed by a physician.
- The device is intended to be used in conjunction with a hollow fiber or parallel plate dialyzer.

Technological Characteristics:

The System 1000® and AltraTouch™ 1000 single patient hemodialysis delivery systems with the Auto Start ★ option are built with the same fluid path and hardware components as the predicate System 1000® and AltraTouch™ 1000 single patient hemodialysis delivery systems. The only difference is a software change to delay the start of heat clean or fluid path rinse. The machine and patient safety systems are the same as the predicate devices. ★

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 1997

Mr. Thomas D. Kelly
Senior Manager of Marketing and
Regulatory Affairs
Althin Medical, Inc.
13520 S.E. Pheasant Court
Portland, Oregon 97222-1298

Re: K964922
Auto Start Disinfection Option - modification of the
Altra Touch™ and Drake Willock® System 1000®
Dialysate Delivery Machines
Dated: March 21, 1997
Received: March 24, 1997
Regulatory class: III
21 CFR §876.5860/Product code: 78 KDI

Dear Mr. Kelly:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4616. 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,

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

510(k) Number K964922

Device Name: Drake Willock® System 1000® Dialysis Delivery System with Auto Start Disinfection Option

AltraTouch™ 1000® Dialysis Delivery System with Auto Start Disinfection Option

Indications For Use:

Indications for use of the Drake Willock® System 1000® Dialysis Delivery System with Auto Start Disinfection Option and AltraTouch™ 1000® Dialysis Delivery System with Auto Start Disinfection Option:

The indications for use of the device are to provide hemodialysis treatments in the acute and chronic setting including high flux hemodialysis.

- The device is intended to be used by trained operators when prescribed by a physician.
- The device is intended to be used in conjunction with a hollow fiber or parallel plate dialyzer.
- The auto start option is intended to allow up to a three day delayed start of the fluid path heat clean or rinse cycle.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Nottling
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K964922

Prescription Use ✓ OR Over the Counter Use ____
(Per 21 CFR 801.109)