K970446

510(k) SUMMARY

JUN - 2 '97

Date:

January 28, 1997

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® Dialysis Delivery System with Hematocrit and Blood Volume Monitor Option

AltraTouch™ 1000 Dialysis Delivery System with Hematocrit and Blood Volume Monitor Option

Common Name:

Dialysis Delivery System

Classification Name:

Hemodialysis System and accessories, Class III Device.

Product code:

78KDI

Equivalence Information:

The Hematocrit and Blood Volume (HCT/BV) Monitor feature is a modification to the predicate System 1000®/AltraTouch™ 1000 dialysis delivery system [510(k) numbers K910215 System 1000® Dialysis Delivery System, K954987 AltraTouch™ 1000 machine and K955384 SND option.] that integrates the stand-alone Crit-Line™ II Instrument for measuring hematocrit (Hct), percent blood volume change (ΔBV), oxygen saturation (O_2 Sat) and access recirculation [510(k) numbers K924167 Crit-Line I with Blood Chamber, K935958 Blood Chamber with E-Beam, K950942 Crit-Line II with Hematocrit Alarm feature and K953875 Crit-Line II with Access Recirculation feature.] into the dialysis delivery system. ★

The primary reason for making the modification is to provide the medical professional with a means of monitoring patient hematocrit, percent blood volume change, oxygen saturation values and access recirculation together with treatment data from the System 1000®/AltraTouch™ 1000 machine during acute and chronic hemodialysis.

The HCT/BV Monitor printed circuit board (PCB) has the identical circuit design as the Crit-Line II™ Instrument PCB. The board has been laid out to fit in the System 1000®/ AltraTouch™ 1000 mother board circuit card cage. The integrated HCT/BV Monitor PCB will utilize the user interface and display of the System 1000®/AltraTouch™ 1000 Dialysis Delivery Systems. The integrated HCT/BV PCB will utilize the internal power

supply of the System 1000®/AltraTouch™ 1000 machine instead of batteries or external power supplies as the stand-alone Crit-Line™ Instrument (predicate device) does.

The Blood Chamber is the same as the Crit-Line™ Blood Chamber. The label has been modified to include the Althin name for business reasons. In-Line Diagnostics will manufacture the blood chamber for Althin Medical Inc. under the name AltraCrit™ Blood Chamber.

This submission also details an external communication software package call the "HCT/BV Monitor Print Utility" to transfer hematocrit (Hct), percent blood volume change (ΔBV), oxygen saturation (O_2 Sat) and access recirculation data in an ASCII file from the host System 1000®/AltraTouch™ 1000 delivery system to a standard PC computer disk. The Print Utility serves the identical purpose as the Procomm® software communication package currently utilized by Crit-Line II™ Instrument.

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

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

Device Description:

The System 1000® and AltraTouch™ 1000 devices are Single Patient Dialysis Delivery Systems for hemodialysis. The systems fulfill 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.

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

The System 1000® and AltraTouch™ 1000 Dialysis Delivery System with HCT/BV Monitor, integrates two 510(k) approved devices into one device. [System 1000®/AltraTouch™ 1000 Dialysis Delivery System: K910215, K954987 and K955384; andCrit-Line Instrument: K924167, K950942 and K953875] This device provides the care giver with the option to monitor hematocrit, percent blood volume change, oxygen saturation value and access recirculation. The HCT/BV Monitor uses a light emitter/light detector sensor connected to a sterile disposable Blood Chamber (Crit-Line™ Blood Chamber: K924167 and K935958) in the extracorporeal blood circuit. The sensor detects various absorption and scattering characteristics exhibited by the blood. Data from the intergraded HCT/BV Monitor are communicated to the host System 1000®/AltraTouch™ 1000 machine via the serial communication port (RS232) and displayed on CRT/LCD screen of the System 1000®/AltraTouch™ 1000 machine.

The HCT/BV Monitor option alerts the operator with audible and visual alarms if the patient's hematocrit is equal or exceeds the operator set hematocrit alarm limit or if the patient's blood volume is equal or lower than the operator set blood volume alarm limit.

Intended Use

Intended use of the System 1000®/AltraTouch™ 1000 Delivery System

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 of the stand-alone Crit-Line™ Instrument ★

The intended use of the device is to determine hematocrit, percent blood volume change, oxygen saturation and access recirculation values by attaching the Crit-Line™ Sensor to a

Crit-Line™ Blood Chamber that has been inserted into the patient's extracorporeal blood tubing.

Intended use of the System 1000®/AltraTouch™ 1000 Delivery System with the HCT/BV Monitor 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.
- The HCT/BV Monitor option is intended to be used when hematocrit, blood volume, oxygen saturation monitoring and access recirculation determination are chosen for use in chronic or acute hemodialysis treatments.

Technological Characteristics

Althin Medical is integrating a technology invented by In-Line Diagnostics to measure hematocrit (Hct), percent blood volume change (ΔBV), oxygen saturation (O_2 Sat) and access recirculation. Crit-Line™ is the trade name for this technology. The technology is based on the absorption characteristics of blood at three different wavelengths. Components of this technology are a sensor clip, a disposable (blood chamber), and an electronics assembly. This technology was integrated into the System 1000®/ AltraTouch™ 1000 dialysis delivery system. This technology will be offered as an option to new equipment as well as a retrofit kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUN - 2 1997

Re: K970446
Drake Willock® System 1000® and AltraTouch™
1000 Dialysis Delivery Systems with Hematocrit
and Blood Volume Option
Dated: May 14, 1997
Received: May 16, 1997
Regulatory class: III and II
21 CFR §876.5860/Product code: 78 KDI
21 CFR §876.5820/Product code: 78 MQS
21 CFR §864.6400/Product code: 81 JPI

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,

Lilian 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 (if known): K970446

Device Name: Drake Willock® System 1000® Dialysis Delivery System
AltraTouch™ 1000 Dialysis Delivery System
with Hematocrit and Blood Volume Option

Indications For Use:

Indications for Use of the System 1000®

- 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 use in conjunction with a hollow fiber or parallel plate dialyzer.

Indications for Use of the Hematocrit and Blood Volume Monitor Option

The intended use of this device is to monitor Hematocrit, Percent Blood Volume Change, Oxygen Saturation value, and Access Recirculation.

- The device is intended to be used as an integrated option of the System 1000® Dialysis Delivery System.
- 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 the Crit-Line disposable Blood Chamber. The Blood Chamber is a non reusable device.
- To provide the medical professional with a means of monitoring Hematocrit, Percent Blood Volume Change, Oxygen Saturation value, and Access Recirculation during hemodialysis treatment.

(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 21 CFR 801.109)

Robert R Nathan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970446

(Optional Format 1-2-96)