

AUG - 8 1996

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

Applicant Information:

Date Prepared: October 18, 1995

Name: Althin Medical, Inc.

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Device Information:

Trade Name: AltraTouch™ 1000 Single Patient Hemodialysis Delivery System

Common Name: As above.

Classification Name: Hemodialysis Delivery System

Equivalent Device:

Drake Willock® System 1000® Single Patient Hemodialysis Delivery System

Device Description:

A hemodialysis delivery system which will provide dialysate at the prescribed temperature and ionic concentration to be used for hemodialysis treatment. It has the ability to monitor machine, dialysate, and blood circuit functions during dialysis. The machine treatment parameters are displayed on a Liquid Crystal Display monitor screen. The operator controls is done through a interactive touch screen.

Intended Use:

To provide hemodialysis treatment to patients with acute or chronic renal failure.



The Althin Group

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Comparison To Predicate Device:

The AltraTouch™ 1000 Single Patient Hemodialysis Delivery System is a modification of the Drake Willock® System 1000 Single Patient Dialysate Delivery System {510(k) number K910215}, the predicate machine. The modifications consist of:

1. Replacing the 12 inch (diagonal) Cathode Ray Tube display of the predicate machine with a 9 1/2 inch (diagonal) Liquid Crystal Display (which lowers the overall height of the machine by approximately two inches, and reduces its overall weight by approximately 31 pounds).
2. Reducing the maximum dialysate flow rate by 20%.
3. Increasing the minimum temperature requirement for the incoming water, and offering some of the features that are standard on the predicate machine as options.

Except for the parts associated with the change to the LCD screen, the AltraTouch™ 1000 machine is built from the same parts as the predicate device. The only software changes are those that control the display color pallet. All machine/patient safety systems are identical to the predicate device. Althin Medical, Inc. believes that the design and testing of this modified System 1000® machine demonstrates that it is safe and effective.