

JAN 10 1997

## 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: K955384

### **Applicant Information:**

Date Prepared: November 21, 1995  
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### **Device Information:**

Trade Name: Drake Willock® System 1000® Dialysate  
Delivery System with Single Needle Single Lumen option  
Common Name: As above.  
Classification Name: Hemodialysis System and Accessories.

### **Devices to Which Substantial Equivalence is Being Claimed:**

The Single Needle Single Lumen option for the System 1000 Hemodialysis Machine is substantially equivalent to the following products, which are currently legally marketed medical devices.

1. Drake Willock 8810 Single Needle Device  
Althin Medical, Inc. (K873279)
2. Drake Willock 8806 Single Needle Device  
Althin Medical, Inc.
3. Fresenius A 2008 D Single Needle Device  
Fresenius, USA
4. Hospal BSM 22  
Hospal, France



The Althin Group

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Drake Willock® dialysis equipment  
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**Device Description:**

This application is for adding the option of Single Needle Single Lumen dialysis treatment to the current System 1000<sup>®</sup> Hemodialysis Machine. Single Needle Single Lumen dialysis is performed by controlling blood flow into and out of the patient with a single needle single lumen blood access, as opposed to dialysis blood access with two needle punctures. Because of the single lumen access, the hemodialysis machine operates cyclically, i.e. part of the time blood is aspirated from the patient (arterial phase), and part of the time blood is infused to the patient (venous phase).

**Arterial Phase:** During the arterial phase, the venous blood line is clamped, and blood is pumped via the peristaltic blood pump from the patient into the machine's extracorporeal circuit, and into (a) holding chamber(s) until a predetermined volume of blood has been accumulated. When the specified volume has been reached, the blood pump is stopped. The arterial phase is now complete.

**Venous Phase:** During the venous phase, the venous blood line is unclamped, the arterial blood line is clamped, and the blood in the holding chamber(s) and extracorporeal circuit is returned to the patient. When the venous pressure reaches a predetermined Low Pressure Trip Point, the venous blood line is clamped. At this point, the system returns to the arterial phase, and the cycle starts again.

Single Needle Single Lumen dialysis can be performed using either one peristaltic blood pump or two. (The Arterial and Venous phases described above apply to either system configuration). In systems using two pumps, the second pump returns the blood to the patient (Venous Phase). In systems using one pump, the pressure difference between the venous drip chamber and the patient causes the blood to return to the patient.

Single Needle Single Lumen dialysis (with systems using either one peristaltic pump or two) can be performed using either one line clamp or two. (The Arterial and Venous phases described above apply to either system configuration.) The second (arterial) clamp is required only when a blood line with an arterial drip chamber is used.

**Intended Use:**

Single Needle Single Lumen Dialysis is indicated for use when a single venipuncture is chosen for use in chronic or acute hemodialysis treatments.

### **Comparison to Predicate Devices:**

The System 1000<sup>®</sup> Single Needle Single Lumen option and the Predicate Devices identified above all have the following technological characteristics in common:

1. Single needle, single lumen blood access.
2. One or two peristaltic blood pumps.
3. One or two line clamps.
4. Cyclic operation: Arterial phase and Venous phase.

All existing safety systems in the System 1000<sup>®</sup> machine are still in place. Additional safety systems have been added to accommodate the hardware and functional changes and additions required for the Single Needle Single Lumen option. Althin Medical, Inc. believes that the design and testing of this device demonstrates that it is safe and effective.