

JUN 3 - 2005



**Summary of Safety and Effectiveness
510(k) Summary
Allient® Sorbent Hemodialysis System**

510(k) K043574

Date of Application April 22 , 2005

Submitters Name Renal Solutions Inc
770 Commonwealth Drive
Warrendale, PA 15086

Contact Name Richard G. Confer, Director of Regulatory Affairs
770 Commonwealth Drive
Warrendale, PA 15086
Phone: 724-772-6900
e-mail: rick.confer@renalsolutionsinc.com

Trade Name Allient® Sorbent Hemodialysis System

Common Name System, Dialysate Delivery, Sorbent Regenerated

Classification Class II per 21CFR876.5600 code FKT

Predicate Device Information REDY 2000 (K840743 and K882428)

Device Description

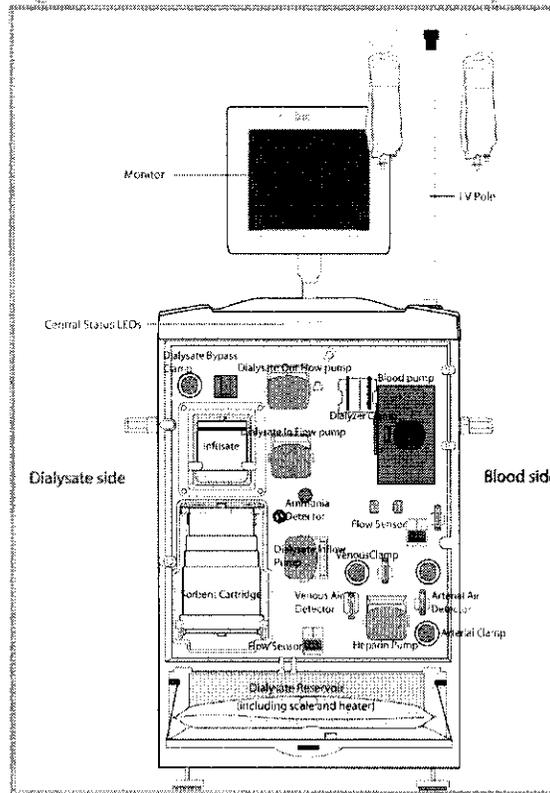
Overview of the Allient® Sorbent Hemodialysis System

The Allient Sorbent Hemodialysis System (Allient System) is intended for the treatment of acute or chronic uremic patients where hemodialysis is prescribed by the physician.

The system consists of the Allient hemodialysis machine, SORB™ series of Sorbent cartridges, a single-use, sterile, disposable blood tubing set, a single-use disposable dialysate set, and various dialysate and infusate chemicals. The system is recommended for use with a variety of dialyzers, access needles or access cannulae, which will be supplied by other manufacturers.

Figure E-1 below is an illustration of the Allient System with major components of the system labeled for clarity.

Figure E-1 Allient Sorbent Hemodialysis System



The Allient System operates in a similar manner to standard hemodialysis systems currently approved for use. The only significant differences between the Allient System and standard hemodialysis machines are as follows:

The Allient System utilizes a Sorbent cartridge to purify dialysate made from potable water. After passing through the dialyzer, the dialysate is recirculated to the dialyzer instead of being disposed of. This contrasts with traditional

“single pass” dialysis, which uses purified water, mixes it continuously with dialysate, and passes it across the dialysate side of a dialyzer membrane in a single flow-through system. Wastewater is routed to a drain and not recirculated. By recirculating and refreshing the dialysate, the Allient System uses 6 liters of water per dialysis treatment. A traditional single-pass dialysis system uses at least 120 liters of purified water during the typical 4-hour dialysis session.

The Allient System utilizes the Pulsar™ air-activated pump in contrast to the roller-activated pump commonly employed in traditional hemodialysis systems. The Pulsar blood pump is a dual-chamber pneumatically operated pump.

All other aspects of Renal Solutions’ Allient Sorbent Hemodialysis System process are identical to those employed in the standard “single pass” method of dialysis: there are no significant differences in the technology employed in Sorbent dialysis therapy between the Allient System and traditional methods.

The Allient System functions as a traditional recirculating Sorbent hemodialysis system, similar to the REDY 2000 System. Either single-needle or dual-needle access to the patient is permitted.

The patient’s blood is pumped from the access through a dialyzer and is returned to the patient. Heparin is administered via a flow-controlled heparin pump capable of delivering rates of 0 to 3 milliliter per hour (mL/hr) in 0.5 mL/hr increments as well as an initial bolus of 0 to 10 mL. Blood-flow rates are settable in 10 milliliter per minute (mL/min) increments in the range of 200 to 400 mL/min in the dual-needle mode and 200 to 300 mL/min in the single-needle mode.

The dialysate delivery system consists of a container for dialysate, Sorbent regenerative cartridges, chemical infusion system to replace chemicals removed by the Sorbent cartridges, and an ultrafiltrate control system. The dialysate delivery system operates in a batch recirculating mode and continuously recirculates the dialysate through the cartridge. The cartridge removes dialyzed toxins from the dialysate and buffers the sodium and bicarbonate levels in the dialysate to maintain normal levels in the patient.

The Acute mode of operation is intended for use in a hospital, acute or chronic-care facility, or dialysis clinic where the patient is continually monitored. The Acute mode of operation allows the clinician or dialysis technician to enter prescription parameters and machine operating parameters for each patient.

The Allient System incorporates a Graphical User Interface (GUI) comprised of a touch-screen display, which controls the System software. The GUI is

used to select the mode of operation of the Allient System and enter prescription data and machine control parameters during setup. This information is stored for future reference and verification prior to subsequent treatments. Treatment status and progress, in addition to machine status, is continually collected and displayed on the GUI screen to support treatment. The GUI's touch-screen technology also provides ease of use for Home patients. The Allient System incorporates a control system that contains a number of safety features and audible and visible alert and alarm functions to warn the operator or patient of unsafe conditions.

Specifications:

Physical Dimensions:

System:

Height 35.49"

Width 27.02"

Depth 21.79"

System with Monitor:

Height: 59.42"

Width: 27.02"

Depth: 21.79"

Monitor (only):

Height (including base): 15.4" (391 mm)

Width: 15.4" (391 mm):

Depth: 8.2" (208 mm)

Monitor Arm (only):

Vertical Adjustment Range: 20" (508 mm)

Panel Extend/retract: 25" (635 mm)

Weight: 23 lbs: (10.4 kg)

System with Cart:

Height: 53.50"

Cart (only)

Height: 18.50"

Width: 26.50"

Depth: 22.0"

Weight:

System:

240 pounds 109 kg

System (with Cart)

282 pounds 128 kg

Environmental Requirements

Operating Conditions:

Operating Temperature

Ambient temperature range: +10°C to +35°C.

Storage Temp: -40°C to +70°C with condensing humidity allowable.

Relative Humidity: 30% to 95% non-condensing.

Atmospheric Pressure: 585 mmHg to 795 mmHg.

Storage Temperature: SORB Cartridges

Long Term: Ambient temperature range: +4°C to +30°C.

Short Term (less than 30 days): -15°C to +45°C

Relative Humidity: 20% to 80% non-condensing storage.

Power

The system operates on fused AC power with the following requirements:

Line voltage: 115-265 VAC

Line Frequency: 50/60 Hz

Power consumption: 12 Amps at 120VAC, 6 Amps at 240 VAC max

Fuse: 12Amps 250V time delay

Leakage Current: less than 300 uA

Electrical Outlet Requirement: Dedicated 15 Amp, three prong, grounded electrical circuit

Power Failure:

Indicated by an audible alarm. The system is capable of continuing operation during a power loss or dip of a minimum of 1 second in length.

Power Loss Recovery:

If the power loss is longer than 1 second, the system will shut down in a safe mode; no log data or treatment data will be lost.

Treatment Requirements:

Water Quality

Six liters of potable water that meets the EPA standard for drinkable water; normally requires no additional water purification.

Flow Rates

Dialysate Flow Rate: 0 to 400 +/- 10% mL/min into 25 psi maximum back pressure from the Sorbent cartridge

Measuring Tolerance: +/- 10% of set point

Increment: 10 mL/min within the range of 200 to 400 mL/min

Infusate Flow Rate: 1:342 of Dialysate flow rate setting (0 - 1.17 mL/min)
Measuring Tolerance: + / - 10% of set point

Heparin Flow Rate: 0 to 3 mL/hr against +/- psi back pressure
Measuring Tolerance: + / - 0.1mL/hr (rates are < 1 mL/hr)
+ / - 10% (rates are \geq 1 mL/hr)
Increment: 0.25 mL/hr increments

Blood Management System:

Blood Flow Rates: Single Needle: 150 mL/min to 200 mL/min
Dual Needle: 150 mL/min to 400 mL/min
Vascular Access Range: up to 17 gauge (dependant on patient access and dialyzer)

Monitoring Systems:

Air Detectors
Air Detection Range greater than 1.0 ml bubble or microbubbles greater than 1.5 ml

Dialysate Temperature Control:

Temperature Range 34o C to 37o C

Blood Leak Detector:

Leak Detection Range: 0.35 ml/min of 0.25% hematocrit Blood in the dialyzer output flow

Saline:

Flow Rate: Controlled at 200 mL/min
Measuring Tolerance: + / - 10% of set point
Selectable Bolus volumes: 110 mL, 220 mL, 330 mL of normal saline

Ultrafiltration:

Net UFR: Min. 20g/hour to 2000 g/hour based on acceptable Dialyzer
Measuring Tolerance: + / - 20 g/hr or 5% whichever is greater based on the set UFR:
Maximum UF 6 Liters

Heparin:

Flow Rate: 0 mL/hr to 3 mL/hr
Vial sizes: 10 mL and 30 mL vial of 1,000 u/mL heparin solution
Flow Rate Accuracy: 10% of set point

Degassing:

Flow Rate: Dialysate flow rate of 750 mL/min with the SORB cartridge

bypassed

Frequency: 0 - 20 seconds

Duration: 0 - 60 minutes

Intended Use The Allient Sorbent Hemodialysis System, including the SORB series and HISORB series cartridges, is to be used for the treatment of acute and chronic uremic patients where hemodialysis is prescribed by the physician.

Summary of Testing

The Allient System has been tested to verify that it meets its specifications as listed above;

The Allient System has also been tested and meets the following domestic and international standards.

Standard	Title
ANSI/AAMI RD17	Hemodialyzer Blood Tubing
ANSI/AAMI RD5	Hemodialysis Systems
EN 556	Sterilization of Medical Devices - Requirements For Terminally-Sterilized Devices To Be Labeled 'Sterile'
IEC 60529	Degrees Of Protection Provided By Enclosures (IP Code) Note: It is agreed that IXP 1 is the level of protection to be afforded by the Allient system.
IEC 60601-1:2003	Medical Electrical Equipment, Part 1- General Requirements for Safety
IEC 60601-1-2:2001	Medical Electrical Equipment - Part 1: 2 General requirements for safety; 4. Collateral Standard: Electromagnetic Compatibility
IEC 60601-2-16:1998	Medical electrical equipment - Part 2: Particular requirements for the safety of hemodialysis, haemodiafiltration and haemofiltration equipment
ISO 10993-10:	Biological evaluation of medical devices -- Part 10: Tests for irritation or intracutaneous Reactivity
ISO 10993-1:1993	Biological evaluation of medical devices – Systemic Toxicity- Material Mediated Pyrogenicity
Iso 10993-3:1993	Biological evaluation of medical devices – Biological evaluation of medical devices, Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity Genotoxicity- Ames test
ISO 10993-10:2002	Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization

ISO 10993-5:1999	Biological evaluation of medical devices -- Part 5: Tests for <i>In Vitro</i> cytotoxicity
ISO 10993-7:1995	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
ISO 11135:1994	Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization
ISO 8638:	Extracorporeal Blood Circuit For Haemodialysers, Haemofilters and Haemoconcentrators

Conclusions All testing performed on the Allient Sorbent Hemodialysis System verifies the substantial equivalency of the Allient System to the predicate REDY 2000 system, when used with the Renal Solutions Sorbent Dialysis (SORB) cartridges for acute and chronic hemodialysis.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 - 2005

Mr. Richard G. Confer
Renal Solutions™, Inc.
770 Commonwealth Drive
Suite 101
WARRENDALE PA 15086

Re: K043574

Trade/Device Name: Allient® Sorbent Hemodialysis System

Regulation Number: 21 CFR §876.5600

Regulation Name: Sorbent regenerated dialysate delivery system for hemodialysis

Regulatory Class: II

Product Code: FKT

Dated: April 18, 2005

Received: April 26, 2005

Dear Mr. Confer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other	-	240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K043754

Indications for Use

510(k) Number (if known): N/A

Device Name: Allient® Sorbent Hemodialysis System

Indications For Use:

The Allient® Sorbent Hemodialysis System, including the SORB™ series and HISORB™ series of cartridges, is to be used for the treatment of acute and chronic uremic patients where hemodialysis is prescribed by the physician.

Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043574

0010