K060381 Page 1 of 2

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

This 510(k) Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The contents of this 510(k) summary have been provided in accordance with 21 CFR 807.92.

MAY 2 4 2006

Date	February 13, 2005
Common/Usual Name	Sorbent Hemodialysis System
Trade/Proprietary Name	Allient® Sorbent Hemodialysis System
Classification Name & Device Classification	System, Dialysate Delivery, Sorbent Regenerated, Class II
Product Code	FKT
21 CFR Reference	876.5600
Owner/Operator	Renal Solutions Inc 770 Commonwealth Drive Warrendale, PA 15086
Contact	David J. Vanella, Vice President Quality Assurance & Regulatory Affairs 770 Commonwealth Drive Warrendale, PA 15086 Phone: 724-772-6900 e-mail: david.vanella@renalsolutionsinc.com
Predicate Device Information	Allient Sorbent Hemodialysis System K043572

Device Description

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

The Allient System functions as a traditional re-circulating sorbent hemodialysis system. Either single-needle or dual-needle access to the patient is permitted. 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 patient's blood is pumped from the access through a dialyzer and is returned to the patient.

Substantial Equivalence

The modified Allient Sorbent Hemodialysis has the following similarities to the Allient Sorbent Hemodialysis which previously received 510(k) clearance:

- have the same indicated use,
- use the same operating principles,
- incorporate the same basic system design,
- incorporates the same accessories and generic materials which are manufactured, packaged, and sterilized using the same processes.

In summary, the Allient Sorbent Hemodialysis System (considering the changes as described within) is, in our opinion, substantially equivalent to the Allient Sorbent Hemodialysis System K043574.

Conclusion

Based on the comparison of technological characteristics to the Allient Sorbent Hemodialysis System and certification to design controls, the modified device is substantially equivalent to the cleared Allient Sorbent Hemodialysis System (K043574). The modifications as described above have been evaluated in terms of both safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 24 2006

Mr. David J. Vanella
Vice President, Quality Assurance & Regulatory Affairs
Renal Solutions®, Inc.
770 Commonwealth Drive
WARRENDALE PA 15086

Re: K060381
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 26, 2006
Received: May 2, 2006

Dear Mr. Vanella:

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

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

Enclosure

K060381

Indications for Use

510(k) Number K060381

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 X AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K860381