SEP 17 2003

Renal Solutions

Appendix 1-B
Summary of Safety and Effectiveness
510(k) Summary
SORB+ and HISORB+ Cartridges

510(k) K031099

Date of Application	March 31, 2003
Submitters Name	Renal Solutions Inc, Sorb Technology Division 3631 SW 54th Street Oklahoma City, OK 73119 USA Phone 405-682-1993 FAX- 405-682-2108
Contact Name	Richard G. Confer, V.P. RA and QA Renal Solutions 770 Commonwealth Drive, Suite 101 Warrendale, PA 15086 e-mail: rick.confer@renalsolutionsinc.com
Trade Name	SORB+ and HISORB+
Common Name	System, Dialysate Delivery, Sorbent Regenerated, Accessory
Classification	Class II per 21CFR876.5600 code FKT
Predicate Device Information	K811170- SORB 3160- manufactured by Sorb Technology K812869-HISORB 3260- manufactured by Sorb Technology

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Appendix 1-B
Summary of Safety and Effectiveness
510(k) Summary
SORB+ and HISORB+ Cartridges

Device Description

Sorbent (or regenerative) dialysis systems use the chemical action of a sorbent cartridge to remove urea and other waste materials from the dialysate and return the fresh dialysate to the dialysate holding tank. This fresh dialysate then passes through a dialyzer, removes additional waste material, and re-circulates through the sorbent cartridge to continue the process. This contrasts to traditional "single pass" dialysis, which uses purified water passing across the dialysate side of a dializer membrane in a single flow-through system to remove urea and other waste materials from the dialysis patient's bloodstream. Wastewater is routed to a drain and not re-circulated. By re-circulating and refreshing the dialysate, the Renal Solutions' REDY System uses 6L of water per dialysis treatment. A traditional single pass dialysis system uses at least 120L of purified water during the typical 4 hour dialysis session.

The SORB+ and HISORB+ Cartridges are intended to be used in a Renal Solutions REDY Sorbent Hemodialysis System as the chemical agents that absorb the urea and other waste material from the dialysate stream. This system is represented schematically in the following diagram.

Two models of SORB Cartridges are available and have sufficient capacity to adsorb patient dialysis waste products presented to them during a usual dialysis procedure within the limits given below. It is recommended that the patient dialyzable volume, pre-dialysis BUN, dialyzer clearance, and treatment time be sufficient to provide the removal of urea-nitrogen within these limits for each model of Sorbant Cartridge:

SORB™ +
The SORB+ Cartridge has an approximate urea-nitrogen capacity of from 9.5 grams to 23.5 grams.
HISORB™ +
The HISORB+ Cartridge has an approximate urea-nitrogen capacity of from 23.5 grams to 35.0 grams. Both cartridges use the same theory of removing toxins from the dialysate. The initial dialysate is made by dissolving the REDY Chem™ dialysate and dialysate additives in six (6) liters of potable (per EPA requirements) water. The REDY Chems are non-sterile, single use, unit dose packages of various weights used individually and in combination according to the physician's prescription of sodium bicarbonate, sodium chloride, dextrose, and ascorbic acid chloramine reducing agent. The resulting dialysate is added to the machine and pumped to the

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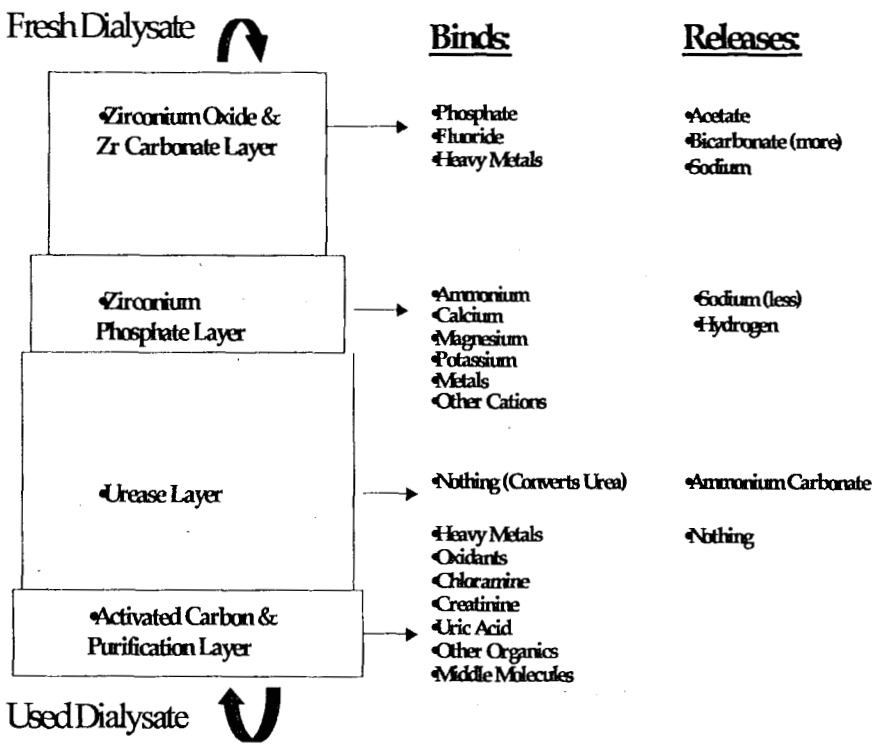
Appendix 1-B
Summary of Safety and Effectiveness
510(k) Summary
SORB+ and HISORB+ Cartridges

dialyzer, taking up the uremic toxins from the patient's blood.

Cartridge Construction



The dialysate, after passing through the dialyzer, passes through the SORB+ (or HISORB+) Cartridge where it is purified and partially regenerated. The SORB+ Cartridges are non-sterile products intended for single use only. They contain, in the first layer, activated carbon (AC) as an absorbent purification material and also as a filler material. The primary purpose of the bulk of the AC is to absorb organic wastes from the patient such pure absorbent with no release of counter ions or effect or dependency on the other layers.

The second layer contains immobilized urease enzyme (IU) that breaks down the patient's waste urea into ammonium carbonate. It contains a natural enzyme and purified alumina that acts to bind and immobilize the enzyme in the Sorbent Cartridge in both a combined and a separate layer.

The next layer, containing the cation exchange material zirconium

Appendix 1-B
Summary of Safety and Effectiveness
510(k) Summary
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phosphate (ZP) removes the ammonium ion from the IU layer and donates sodium and hydrogen ions in a controlled release, which combine with the remaining carbonate ion to make sodium bicarbonate in proper balance for regenerative dialysis. The ZP also removes other cations from the dialysate such as calcium, magnesium, and potassium, which are essential components of the dialysate.

The final layer in the Sorbent Cartridge contains the anion exchange material hydrous zirconium oxide in the acetate counter ion form (HZO) and sodium zirconium carbonate (SZC). These materials remove the waste metabolite phosphate ions and other highly charged anionic metals from both the initial water source and from the patient, such as fluoride and aluminum.

After the purified and partially regenerated dialysate leaves the Sorbent Cartridge, it is fully reconstituted by the machine by re-infusing the calcium, magnesium, and potassium removed by the Sorbent Cartridge. The fully purified and reconstituted dialysate is then continually pumped back to the dialyzer where the cycle starts again.

The clinical result is dependent upon both the cartridge selection and performance, and the dialysate chemical selection and performance working together. That is, it is also dependent in conjunction with rest of the Dialysis Prescription for the specific patient, his/her condition, the dialyzer selection and performance, the dialysate flow rate, the blood flow rate, the ultrafiltration amount and rate, the length of time of dialysis, and the frequency of dialysis.

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Appendix 1-B
Summary of Safety and Effectiveness
510(k) Summary
SORB+ and HISORB+ Cartridges

Intended Use

The SORB+ and HISORB+ Cartridges are to be used only with Renal Solutions' REDY Sorbant Dialysis systems for the treatment of acute and chronic uremic patients where hemodialysis is prescribed by the physician.

Summary of Testing

The SORB+ and HISORB+ Cartridges have been tested for conformance to their design specifications for materials and construction, and chemical performance in simulated patient use conditions. The cartridges also have been tested for their effectiveness in purifying water or dialysate to safe levels for dialysis, biocompatibility, and endotoxin and bacteria removal.

The results of the testing are as follows:

Testing Topic	Reference Standards	Results
Validation of Maximum Allowable Contamination Levels of Toxic Chemicals in Water Supply for the SORB+ and HISORB+ Cartridges	AAMI/ANSI, RD5-1992 and RD62-2000, RD62, 2001	Pass
Limit Test of Endotoxin and Bacteria Removal by SORB+ and HISORB+ Cartridges	AAMI/ANSI	Pass
Biocompatibility Validation of SORB + and HISORB + Cartridges	ISO 10993 cytotoxicity, irritation or intracutaneous reactivity, and systemic toxicity (acute).	Pass
Validation Testing of SORB+ and HISORB+ Cartridges	Sorb Technologies published capacity specifications	Pass

In addition, the performance of the SORB+ and HISORB+ Cartridges was compared to the performance of the current version of the SORB and HISORB Cartridges in in-vitro testing.

The acceptability of the current SORB and HISORB Cartridges for

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Appendix 1-B
Summary of Safety and Effectiveness
510(k) Summary
SORB+ and HISORB+ Cartridges

use in sorbent dialysis systems has been established in clinical testing and during clinical use since their clearance for market. (Refer to K811170 and K812869).

Conclusions

All testing performed on the SORB+ and HISORB+ Cartridges verifies the substantial equivalency of these cartridges to the predicate, SORB and HISORB Cartridges, when used with the Renal Solutions Sorbent Dialysis system for acute and chronic hemodialysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2003

Mr. Richard Confer
Senior V.P. Compliance and Regulatory Affairs
Renal Solutions™, Inc.
770 Commonwealth Drive, Suite 101
WARRENDALE PA 15086

Re: K031099
Trade/Device Name: SORB+ and HISORB+ Cartridges
Regulation Number: 21 CFR §876.5600
Regulation Name: Sorbent regenerated dialysate delivery system for hemodialysis
Regulatory Class: II
Product Code: 78 FKT
Dated: August 12, 2003
Received: August 13, 2003

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 (PMA), it may be subject to 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

K031099

Appendix 1-A

Ver/ 3 - 4/24/96

Applicant: **Renal Solutions, Inc.**

510(k) Number (if known): K031099

Device Name: **SORB+ and HISORB+ Cartridges**

Indications For Use:

The SORB+ and HISORB+ Cartridges are to be used only with Renal Solutions' REDY Sorbant Dialysis systems for the treatment of acute and chronic uremic patients where hemodialysis is prescribed by the physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)

Division 'sign Off

510(k) Number_____

Prescription use ✓ or Over-the-counter____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031099