2008 Sorbent Hemodialysis System

510(k) Premarket Notification

Section 5: 510(k) Summary

AUG 13 2010

Section 5: 510(k) Summary K093362

Official Contact	David J. Vanella Senior Vice President, Quality Systems Renal Solutions, Inc. 770 Commonwealth Drive Warrendale, Pa, 15086 Phone: (724) 720-2840 FAX: (724) 772-6925
Classification Name	System, Dialysate Delivery, Sorbent Regenerated
Regulation Number	876.5600
Product Code	FKT
Common/Usual Name	Sorbent Hemodialysis System
Proprietary Name	2008 Sorbent Hemodialysis System
Predicate Devices	Allient Sorbent Hemodialysis System Fresenius 2008T Hemodialysis System
Reason for submission	New Device

Substantial Equivalence

The 2008 Sorbent Hemodialysis System device has the following key similarities to the predicate devices:

- Intended use
- Environment of use
- Operating principle
- Technology

Renal Solutions has determined that the differences from the predicate devices have no impact on the safety and effectiveness of the device and that the technological characteristics of the 2008 Sorbent System do not raise new types of safety or effectiveness questions. The information provided including design verification, risk management, safety, biocompatibility and comparative testing were performed on the 2008 Sorbent Hemodialysis System to demonstrate the device meets the design requirements and to support substantial equivalence. In summary, the 2008 Sorbent Hemodialysis System is substantially equivalent to the predicate devices.

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The 2008 Sorbent System incorporates the addition of a module that regenerates spent dialysate and delivers clean dialysate to the dialysis system and required modifications to the 2008 dialysis system. A risk analysis has been established for the 2008 Sorbent System and has includes the potential hazards associated with the device where all hazards have been identified and mitigated to acceptable risk levels.

2008 Sorbent System 510(k) Verification (Non-Clinical) Testing Summary

The verification (non-clinical) testing information consists of performance, safety, and software testing that was performed to verify the 2008 Sorbent System meets its performance specifications and to demonstrate the device is substantially equivalent to the established predicate devices.

The following table summarizes the 510(k) verification testing activities performed. These include performance, safety and software testing, which demonstrates by technical examination that the 2008 Sorbent System meets its performance specifications, the designated (FDA Consensus) standard requirements, and the software design input requirements.

510(k) Verification Testing	510(K) Verification Testing Activities
2008 Sorbent System Performance Testing *The 510(k) contains details of the performance (verification) testing and includes the results that support the performance characteristics of the 2008 Sorbent System.*	Functional testing that demonstrates that the device performs as designed and expected, includes the following: • The specific verification tests conducted • A description of all test protocol including: • objective of the tests • test articles used in the tests • test methods and procedures • pre-defined acceptance or pass/fail criteria. • System-level hazard analysis evaluation that confirms that the device does not perform in an unexpected and/or unsafe manner
2008 Sorbent System Safety Testing *The 510(k) contains details of the safety (standards) verification testing and includes the results that support the safety characteristics of the 2008 Sorbent System.* *Biocompatibility testing was performed on all new materials that are patient-fluid contacting*	Product safety testing that demonstrates that the device performs per the FDA Consensus Standards, as identified below: • Electrical safety testing (IEC 60601-1:1988 + A1:1991 + A2:1995 Medical electrical equipment-Part 1:General requirements for safety) • Electromagnetic compatibility (EMC) testing (IEC 60601-2-16: 1998-02 Medical electrical equipment Part 2-16: Particular requirements for the safety of Hemodialysis, haemodiafiltration and haemofiltration equipment) • Biocompatibility Testing (AAMI / ANSI / ISO 10993-1:2003 Biological evaluation of medical devices Part 1: Evaluation & testing) • Risk Analysis (ISO 14971:2007 Medical devices - Application of risk management to medical device)

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510(k) Verification Testing	510(K) Verification Testing Activities
2008 Sorbent System Software Testing *The 510(k) contains details of the software testing and includes the required documentation as required per the document titled "Guidance for the Content of Premarket Submissions for Software".*	Software testing that demonstrates the device software meets the design input requirements. The device was tested and includes the following • Structure chart of flow chart describing software architecture • Summary of software development procedures, including changes made to the software • Software requirements specification with traceability back to the hazard analysis • Verification and validation test plans, including pass/fail criteria and traceability back to the requirements; • System level test results • Current software version number and date of latest revision.

The conclusions drawn from this testing demonstrates that the 2008 Sorbent System is as safe, as effective, and performs at least as safely and effectively as the legally marketed devices identified as predicate devices to which it was compared.

Indications of Use

The 2008 Sorbent System is intended for adult acute and chronic uremic patients in the presence of a healthcare practitioner where hemodialysis is prescribed on the order of a physician.

General Safety and Effectiveness

The intended use for the 2008 Sorbent System is for treatment of adult acute and chronic uremic patients in the presence of a healthcare practitioner where hemodialysis is prescribed on the order of a physician. The operator must be knowledgeable of hemodialysis methodology and relevant physiology, proficient in healthcare procedures, thoroughly familiar with the contents of the Operator's Manual and fully trained and qualified to operate this device.

Device Description

The 2008 Sorbent System is intended for adult acute and chronic uremic patients in the presence of a healthcare practitioner where hemodialysis is prescribed on the order of a physician. The 2008 Sorbent System operates in a similar manner to standard hemodialysis systems currently approved for use; it is substantially equivalent to the Fresenius 2008T hemodialysis machine (K080964) and the Renal Solutions Allient® Sorbent Hemodialysis System (K070739).

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The significant difference between the 2008 Sorbent System and standard single-pass hemodialysis machines is that the 2008 Sorbent System utilizes a sorbent cartridge to purify dialysate made from potable tap water and then regenerates fresh dialysate from spent dialysate (like the Allient Sorbent Hemodialysis System).

The 2008 Sorbent System consists of two distinct components:

the 2008 Machine, and

the SORB™ Module.

The SORB Module is a sorbent dialysate regenerative system that attaches to the 2008 Machine and replaces the machine's existing single-pass dialysate delivery system.

During treatment, used dialysate is chemically reprocessed into fresh, new dialysate and sent back to the dialyzer instead of being sent down a drain. By recirculating and regenerating the dialysate, the 2008 Sorbent System uses less than 15 liters of potable tap water per treatment compared to a standard single-pass system that uses at least 120 liters of purified water during a standard 4-hour dialysis treatment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6
Silver Spring, MD 20993-0002

Mr. David J. Vanella
Senior Vice President, Quality Systems
Renal Solutions, Inc.
770 Commonwealth Drive, Suite 101
WARRENDALE PA 15086

AUG 13 2010

Re: K093362
Trade/Device Name: 2008 Sorbent System
Regulation Number: 21 CFR §876.5600
Regulation Name: Sorbent regenerated dialysate delivery system for hemodialysis
Regulatory Class: II
Product Code: FKT
Dated: August 10, 2010
Received: August 11, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093362

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Section 4: Indications for Use

Section 4: Indications for Use Statement

510(k) Number (if known): ~~N/A~~ K093362

Device Name: 2008 Sorbent System

Indications for Use:

The 2008 Sorbent System is intended for adult acute and chronic uremic patients in the presence of a healthcare practitioner where hemodialysis is prescribed on the order of a physician.

Prescription Use ___X____ (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 K093362