AUG 17 2012

Section 6: 510(k) Summary

510(k) Summary

Submitter's Information

Name	Renal Solutions, Inc.
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Official Contact	David J. Vanella Senior Vice President, Quality Assurance & Regulatory Affairs
Date Prepared	5/18/2012

Device Information

Name	Venofer Pump
Common/Usual Name	Hemodialysis System
Product Code	KDI
Classification Name	Dialyzer, High Permeability With Or Without Sealed Dialysate System
Regulation Number	876.5860
Proprietary Name	Venofer Pump
Unmodified Device	Venofer Pump (K103564)
Reason for Submission	Modifications were made to support the use of an additional Blood Tubing Set, the Medisystems Streamline® (K080807).

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Indication for Use

The Venofer Pump is an optional accessory for use with the Fresenius 2008 Series Hemodialysis Machines and is intended to administer Venofer® to treat iron deficiency anemia in patients with chronic kidney disease undergoing hemodialysis, where Venofer®, in conjunction with hemodialysis, is prescribed by a physician.

Device Description

The Venofer Pump is an optional module for use on Fresenius 2008 Series Hemodialysis Machines and is designed to administer Venofer® during dialysis treatments and consists of a control panel, vial holder, fluid detector, and a peristaltic pump. The module is a self contained microprocessor controlled device that receives its power from the Fresenius 2008 Hemodialysis machine.

The Venofer Pump is to be used in accordance with the approved Venofer Indications for Use and the physician's prescription.

Substantial Equivalence

The Venofer Pump 1.3 is substantially equivalent to the unmodified device (Venofer Pump K103564) in terms of its intended use, environment of use, operating principles, and technology. The Venofer Pump is currently used with Fresenius CombiSet Blood Tubing Sets. Modifications were made to support the use of the Venofer Pump with Medisystems Streamline® Blood Tubing Sets (K080807).

Venofer Pump 510(k) Verification Testing Non-Clinical Summary

The verification (non-clinical) testing information consists of the performance, safety, and software testing that was performed to verify the Venofer Pump 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 Venofer Pump meets its performance specifications, the designated (FDA Consensus) standard requirements, and the software design input requirements.

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510(k) Verification Testing	510(K) Verification Testing Activities
Venofer Pump Performance Testing *The performance (verification) test results support the performance characteristics of the Venofer Pump.*	Functional testing was performed to demonstrate that the device performs as designed and expected. The following information is included: • Specific verification tests conducted • Description of the acceptance criteria • System-level hazard analysis that confirms that the device does not perform in an unexpected and/or unsafe manner
Venofer Pump Safety Testing *The verification test results support the safety characteristics of the Venofer Pump.* *Biocompatibility testing was performed on all new materials that are patient-fluid contacting*	Product safety testing demonstrates that the device performs per the FDA Consensus Standards, as identified below: • Electromagnetic compatibility (EMC) testing (IEC 60601-1-2: 2007 – Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements for Testing • Biocompatibility Testing (AAMI / ANSI / ISO 10993-1:2009 Biological evaluation of medical devices Part 1: Evaluation & testing)
Venofer Pump Software Testing *The testing includes the required documentation as described in the guidance titled Guidance for the Content of Premarket Submissions for Software*	Software testing demonstrates the device software meets the design input requirements. The following documents were reviewed and updated: • Software architecture • SDD • Unit test • System and software requirements • Software release history • Traceability

The conclusions drawn from this testing demonstrate that the Venofer Pump is as safe, as effective, and performs as safely and effectively as the legally marketed devices identified as predicate devices to which it was compared.

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General Safety and Effectiveness

The Venofer Pump 1.3 is an updated version of the Venofer Pump (K103564). The performance and technological characteristics of the modified device are equivalent to those of the unmodified device and raise no new types of safety or effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 17 2012

Mr. David Vanella
Senior Vice President QA/RA
Renal Solutions, Inc.
770 Commonwealth Drive, Suite 101
WARRENDALE PA 15086

Re: K121497
Trade/Device Name: Venofer Pump
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: May 21, 2012
Received: May 21, 2012

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,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 5: Indications for Use

Indications for Use Statement

510(k) Number (if known): ~~N/A~~ K121497

Device Name: Venofer Pump

Indications for Use:

The Venofer Pump is an optional accessory for use with the Fresenius 2008 Series Hemodialysis Machines and is intended to administer Venofer® to treat iron deficiency anemia in patients with chronic kidney disease undergoing hemodialysis, where Venofer®, in conjunction with hemodialysis, is prescribed by 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, Gastro-Renal, and Urological Devices

510(k) Number K121497