## Section 5: 510(k) Summary

# 510(k) Summary

JUL - 9 2010

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| **Official Contact** | David J. Vanella<br>Senior Vice President, Quality Systems<br>Renal Solutions, Inc.<br>770 Commonwealth Drive<br>Warrendale, Pa 15086<br>Phone: (724) 720-2840<br>FAX: (724) 772-6925 |
| **Date** | July 8, 2010 |
| **Classification Name** | Dialyzer, High Permeability With Or Without Sealed Dialysate System |
| **Regulation Number** | 876.5860 |
| **Product Code** | KDI |
| **Common/Usual Name** | Hemodialysis System |
| **Proprietary Name** | Fresenius Model 2008T Hemodialysis Machine |
| **Predicate Devices** | Allient 1500 Sorbent Hemodialysis System<br>Fresenius 2008T Hemodialysis System |
| **Reason for submission** | New Device |

## *Substantial Equivalence*

The addition of the Venofer Pump Module on the Fresenius Model 2008T Hemodialysis Machine leverages the company's Heparin Pump design previously used in the Allient 1500 Sorbent Hemodialysis System. The proposed predicate device for the Venofer Pump Module is the Heparin Pump, a component of the Allient 1500 Sorbent Hemodialysis System that was cleared by the FDA in 2007 under K070739.

The Venofer Pump Module device is substantially equivalent to the predicate device in terms of the following:

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

Like the Heparin Pump, the Venofer Pump Module is not a stand alone device. The Venofer Pump Module cannot operate unless it is connected to the 2008T Hemodialysis Machine. In addition, similar to the Heparin Pump, the Venofer Pump delivers the contents of the vial into the extracorporeal blood set (not directly into

the patient). Therefore, similar to the Heparin Pump, the Venofer Pump is considered an accessory to the Fresenius Model 2008T Hemodialysis Machine and thus would also carry the same classification as KDI, 876.5860.

## *Indication for Use*

Fresenius Model 2008T Hemodialysis Machine is indicated for acute and chronic dialysis therapy.

## *Intended Use/General Safety and Effectiveness*

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

## *Non-Clinical Testing*

The non-clinical testing submitted, referenced, and relied on in this 510(k) premarket notification included verification, safety, performance and software testing of the Venofer Pump module as part of the Fresenius 2008T Hemodialysis System. The conclusions drawn from this testing demonstrates that the Fresenius 2008T Hemodialysis 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.

## *Device Description*

The Venofer Pump Module is an optional module for use on Fresenius 2008T Hemodialysis Machines. The module is designed to administer Venofer, an iron sucrose supplement, during dialysis treatments. The Venofer Pump Module is to be used in accordance with the approved Venofer Indications for Use and the physician's prescription.

The Venofer Pump Module is intended to provide ease and consistent delivery of Venofer, an iron sucrose supplement, indicated for the treatment of iron deficiency anemia for Hemodialysis dependent-chronic kidney disease patients. Anemia commonly occurs in patients with chronic kidney disease undergoing Hemodialysis and effective anemia management is recognized as an important factor in improving the outcomes of these patients. Iron deficiency is a frequent contributing factor which complicates the treatment of anemia in chronic kidney disease patients. Iron sucrose is commonly delivered to improve iron status in patients who have chronic kidney disease. Venofer is an injectable iron preparation drug approved for treatment of iron deficiency and is the most commonly used drug to treat iron deficiency anemia in dialysis patients. Renal Solutions has developed the Venofer Pump Module that provides the means to deliver Venofer when undergoing Hemodialysis on a Fresenius 2008T Dialysis System.

The Venofer Pump Module fits into the module compartment of existing Fresenius 2008T Machines and consists of a control panel, vial holder, fluid detector, and a peristaltic pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. David J. Vanella
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Renal Solutions®, Inc.
770 Commonwealth Drive, Suite 101
WARRENDALE PA 15086

JUL - 9 2010

Re: K093964
Trade/Device Name: Fresenius 2008T Hemodialysis Machine with Venofer Pump Module
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: July 7, 2010
Received: July 8, 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,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Section 4: Indications for Use Statement

# Indications for Use Statement

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

**Device Name:** Fresenius 2008T Hemodialysis Machine with Venofer Pump Module

**Indications for Use:**

Same as K080964

Fresenius 2008T is indicated for acute and chronic dialysis therapy.

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 K093964