Fresenius Medical Care

510(k) Summary

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR Part 807.92.

Submitters Information

Name:	Fresenius Medical Care North America
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(781) 699-4479
Fax:	(781) 699-9635
Contact Person:	Denise Oppermann, Senior Director Regulatory Affairs - Devices Renal Therapies Group
Date of Preparation:	17 February 2012

Device Name

Trade Name:	Fresenius 2008T Hemodialysis Machine
Common Name:	Hemodialysis Delivery System
Classification Name:	High Permeability Hemodialysis System
Classification Number:	Class II per § 876.5860
Product Code/Classification Panel:	78KDI/Gastroenterology/Urology Panel

Legally Marketed Predicate Device (Unmodified Device)

Fresenius 2008T Hemodialysis Machine (K113427).

Fresenius Medical Care

Device Description

The Fresenius 2008T Hemodialysis Machine (K113427) is indicated for acute and chronic dialysis therapy. It is designed to provide hemodialysis treatment by controlling and monitoring both the dialysate and extracorporeal blood circuits. In the extracorporeal blood circuit, blood is continuously circulated from the patient through a dialyzer, where toxins are filtered out through a semi-permeable membrane, and returned to the patient. During this process, the extracorporeal blood circuit is monitored for venous and arterial blood pressures, and for the presence of air and blood.

The display screen of the 2008T Hemodialysis Machine is shared between the hemodialysis machine and the CDX PC (optional) running the third party MDDS (Medical Device Data Systems) program. The blue CDX Key located on the fold-down keyboard allows switching between the Dialysis Screen and the MDDS screen. The user interface of the 2008T machine which includes a keyboard, touchpad and touch-screen, is operational in both the dialysis mode and the CDX mode, whichever is actively displayed.

Modifications to the previously cleared 2008T Hemodialysis Machine include:

- **Heparin and Sodium Variation System (SVS) Status:** Addition of visual indication (display) on the home screen and dialysate screen.
- **Dialysate Flow Button:** Addition of Dialysate Flow ON-OFF button in the Dialysate Screen.
- **Applications Installed - Display**: Addition of text identifying which applications (Apps) have been loaded is added to the machine's opening screen.
- **Configurator:** Software modification to support the transfer of machine configuration information between machines during installation or upgrade in service mode.
- **Sodium Variation System (SVS) as an Optional Feature:** Addition of SVS selection in service mode to make the existing SVS feature optional.

The following modification was implemented following a regulatory assessment that the change did not affect the fundamental scientific technology or intended use of the device. Based on FDA guidance "Deciding When to Submit a 510(k) for a Change to an Existing

Device", Fresenius Medical Care North America determined that this modification did not necessitate a 510(k) submission:

- **Wireless Adapter:** A dual band (i.e. 2.5Ghz and 5Ghz) wireless adapter provides the wireless network link for the CDX PC, and supports 802.11a/b/g/n. This new wireless adapter replaces the obsolete wireless adapter (unmodified device) and maintains the latest wireless technology.

Additionally, this submission includes minor maintenance modifications made to the Functional Board Software (V.2.34) of the 2008T Hemodialysis Machine since the last clearance (K113427).
Treatment modalities for the modified Fresenius 2008T Hemodialysis Machine remain identical to those for the unmodified 2008T (K113427):

> The 2008T Hemodialysis Machine is a hemodialysis system used for the treatment of patients with acute or chronic kidney failure, fluid overload or toxemic conditions. Therapies include hemodialysis, hemofiltration and hemo-concentration. The 2008T Hemodialysis Machine will accommodate the use of both low flux and high permeability, high flux dialyzers.

Indications for Use

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

Technological Characteristics

There are no changes to the technological characteristics of the unmodified Fresenius 2008T Hemodialysis Machine. The modified Fresenius 2008T Hemodialysis Machine that is the subject of this submission incorporates software modifications to address user preferences and provide additional user convenience (ease of use).

These modifications do not impact the safety and effectiveness of the device. These software modifications do not expand the capability or change the performance of the 2008T Hemodialysis Machine (K113427) and its intended use/indications for use. The

modified device is equivalent to the un-modified device in terms of water requirements, module options, functional options, performance limits, control parameters, compatible bloodlines, and language options.

The following technical specifications of the modified device remain the same as the unmodified device:

- Safety system
- System performance
- Environmental Requirements
- Transportation and Storage condition
- User Interface (except proposed modifications)
- Hardware and therapy settings
- Accessories
- Environmental Design
- Alarms
- Accuracy and Controls
- Protection against Mechanical Hazard
- Protection against Electrical Hazard
- Protection against excessive temperature or other hazards
- Manufacturing location and manufacturing processes (assembly, fabrication, testing, shipping, installation and service).

A risk analysis has been completed and potential hazards associated with the modifications are identified and mitigated. Mitigations are verified wherever applicable. All potential risks were deemed acceptable after mitigation. Performance and safety tests were conducted to ensure the safety and effectiveness of the device after the proposed modifications.

Performance Data

The performance of the modified device was evaluated according to existing FMCNA procedures, protocols, declared performance standards and guidelines of the quality system regulation (21 CFR 820). Design verification and validation tests were conducted to

ensure that the modifications described in this submission did not affect the essential performance of the device and the device functions as intended.

The following tests were conducted:

Software Verification and Validation Testing

- Software Verification (Functional Tests)
- Regression
- Safety Systems Verification
- Simulated Dialysis Treatment
- Production Test Procedure
- Unstructured and Static Code Verification

Summative Usability Testing

Conclusion

Test results demonstrated that the modified 2008T Hemodialysis Machine functions as intended and met pre-determined acceptance criteria. Results of functional validation, summative usability testing and risk analysis indicate that the modified Fresenius 2008T Hemodialysis Machine is substantially equivalent to the named predicate device and remains safe and effective for its intended use.

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

Ms. Denise Oppermann
Senior Director, Regulatory Affairs Devices
Fresenius Medical Care, North America
920 Winter Street
WALTHAM MA 22451

MAR - 6 2012

Re: K120505
Trade/Device Name: Fresenius 2008T Hemodialysis Machine
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: February 17, 2012
Received: February 21, 2012

Dear Ms. Oppermann:

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

Indications for Use Statement

510(k) Number (if known): K120505

Device Name:
Fresenius 2008T Hemodialysis Machine

Indications for Use:

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

☒ Prescription Use
(Per 21 CFR 801 Subpart D)

AND/OR

☐ Over-the-Counter Use
(21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120505