Fresenius Medical Care

Section 5 510(k) Summary

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

A. Submitter's Information

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Contact Person:	Denise Oppermann, Senior Director Regulatory Affairs - Devices Renal Therapies Group
Date of Preparation:	18 November 2011
Name:	Fresenius Medical Care North America
Address:	920 Winter Street Waltham, MA 02451-1457

B. Device Name

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

C. Legally Marketed Predicate Device (Unmodified Device)

Fresenius 2008T Hemodialysis Machine (K111639).

D. Device Description

The Fresenius 2008T Hemodialysis Machine (K111639) 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, the 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.

In the dialysate circuit, the dialysate acid and bicarbonate concentrates are mixed with purified water in predefined ratios, heated, degassed, and delivered to the dialyzer. Balancing chambers ensure that the incoming flow of the dialysate is volumetrically equal to the outgoing flow in order to control ultrafiltration from the patient.

The front of the machine, with three main sections, contains all of the controls the operator needs access to during a hemodialysis treatment.

The top section of the 2008T Hemodialysis Machine contains the control panel and houses the computer, which runs the treatment program and the separate CDX PC board, which provides the platform for users to utilize medical information software of their choice. The CDX PC is physically located in the 2008T machine's cabinet, but operates independently of the 2008T machine with no capacity to either control the operation of the 2008T hemodialysis machine or influence its programming.

The control panel includes the touchscreen display, fold-down keyboard, touchpad and keypad which allow the operator/user to control the operation of machine by aiding the setting of treatment parameters, monitoring treatment and patient status during dialysis.

The center section contains the modules used for the safe transfer of blood to and from the dialyzer. Dialysate management occurs in the bottom section of the 2008T hemodialysis machine, where the acid and bicarbonate concentrates used to make up the dialysate are mixed and pumped to the dialyzer.

Modifications to the previously cleared 2008T Hemodialysis Machine (K111639) include:

1. CDX as an Optional Feature

The existing CDX PC allows the user the convenience of a PC, running a Windows or Linux operating system and a compatible MDDS, within the same cabinet as the 2008T machine. The modifications are made to make the 2008T Hemodialysis Machine configuration without the CDX feature similar to a previous configuration of the 2008T (TUI; K080964) which did not contain the additional PC board. The CDX PC hardware module is removed from the 2008T user interface board to implement this configuration. Software modifications are made to the functional and user interface board to support the proposed machine configuration ("No CDX" option). The CDX feature will be made available as an upgrade with the supporting hardware and software upon customer request. The 2008T Hemodialysis Machine without CDX configuration performs identically to the unmodified device (K111639), except that users will be unable to access the third party MIS systems.

2. Proposed maintenance changes

The following modifications were implemented following a regulatory assessment that the changes 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", FMCNA determined that these modifications did not necessitate a 510(k) submission:

Fn Lock Keyboard

The existing fold-down compact keyboard used on the 2008T Hemodialysis Machine (K111639) is located directly below the display screen. The keyboard folds down to allow the operator to enter treatment parameter values, chart with CDX or make selections inside the treatment screen and folds up again to prevent unintentional changes.

For added user convenience while navigating their MIS systems, FMCNA added function lock capability to the current 2008T's keyboard. The modification includes repurposing the "Fn" key to a "Fn Lock" key and adding a function lock indicator light to the immediate right of the Caps Lock indicator light. Software and hardware modifications were made to implement this feature. This feature is only available in 2008T Hemodialysis Machines with activation of the CDX option. In dialysis mode, the Fn Lock LED will be off and the function lock feature will be off. In addition, the keyboard is now equipped with a new elastomer material with high tear resistant

properties as compared to the standard silicon elastomer of the existing keyboard in the unmodified device (K111639).

Treatment modalities for the modified Fresenius 2008T hemodialysis machine remain identical to those for the unmodified 2008T (K111639):

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

E. Indications for Use

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

F. Technological Characteristics

There are no changes in the technological characteristics of the previously cleared Fresenius 2008T Hemodialysis Machine (K111639). The modified Fresenius 2008T hemodialysis machine incorporates changes pertaining only to "Software or Firmware" and reliability for the user interface. All water requirements, module options, functional options, performance limits, control parameters, compatible bloodlines, and language options remain unchanged from the predicate device.

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 for the Fn Lock feature)
- Hardware and therapy settings
- Accessories
- Environmental Design
- Alarms
- Accuracy and Controls
- Protection against Mechanical Hazard
- Identification, marketing and documentation due to changes
- Protection against Electrical Hazard

- Protection against excessive temperature or other hazards
- Manufacturing location
- Manufacturing process (assembly, testing, shipping, installation, and service)

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

G. Performance Testing

The performance of the 2008T machine with CDX as an optional feature (and all other modifications discussed in the scope of this submission) 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 testing were conducted to ensure that the modifications described in this submission will not impact the essential performance of the device and the device functions as intended.

The following tests were conducted:

1. Software Verification and Validation Testing

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

2. Safety Testing

- EMC Testing (ESD immunity, emissions)

3. Unit Testing (Fn Lock Keyboard)

4. Physical Testing (Fn Lock Keyboard)

- High Tear Elastomer: Use Life (Shelf Life)
- High Tear Elastomer: Life cycle

H. Conclusion

The test results demonstrated that the modified 2008T Hemodialysis Machine functioned as intended and met pre-determined acceptance criteria. Results of functional and software validation, performance testing, risk analysis, and usability evaluation 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

Food and Drug Administration
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Document Mail Center - WO66-G609
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Ms. Denise Oppermann
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Fresenius Medical Care, North America
920 Winter Street
WALTHAM MA, 02451

DEC 2 1 2011

Re: K113427
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: November 18, 2011
Received: November 21, 2011

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,

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

Section 4 **Indications for Use Statement**

510(k) Number (if known): K113427

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)

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 K113427