Fresenius Medical Care

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

I. Submitter's Information

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Date of Preparation:	10 June 2011

J. Device Name

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

K. Legally Marketed Predicate Device (unmodified device)

Fresenius 2008T Hemodialysis Machine (K093902).

L. Device Description

The Fresenius 2008T Hemodialysis Machine (K093902) 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 before being 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.

Modifications to the previously cleared 2008T Hemodialysis Machine include:

4) **Touch screen user interface:**

The display screen is a component of the control panel located at the top front section of the 2008T Hemodialysis machine. It provides a means of setting treatment parameters and monitoring the treatment and patient status during dialysis. The navigation system software for the touch screen user interface was embedded in the 2008T Hemodialysis Machine since the last 510(k) clearance (K093902). FMCNA intends to activate the use of touch screen functionality for enhanced navigation and user interface. There is no change in the functions of the any of the components of the control panel except the use of touch screen. There are no hardware or software changes required to activate the use of the touch screen navigation. The 15-inch LCD, touch-capable display screen is the same as that previously cleared with the 2008T Hemodialysis Machine (K093902).

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", Fresenius Medical Care North America determined that the modifications described below did not necessitate a 510(k) submission.

5) **Dialysate Sample Port:**

The dialysate sample port is a special connector designed to mount on the dialyzer supply line. It allows the operator/nursing staff to conveniently draw a dialysate sample to test for conductivity, pH, and residual disinfectant before each dialysis treatment.

6) **Shunt Interlock System and modified Hansen Connector:**

The dialyzer supply line (blue) and the dialyzer return line (red) connect to the hydraulics of 2008T hemodialysis machine through a shunt interlock during disinfection and between dialysis treatments. The Hansen connector is a part of the dialysate line. It is a standard connector, specified in ISO 8637:2004, for connecting a dialysate line to the dialysate port of the dialyzer. The Hansen connectors are modified with new "trigger" style easy grip handles, facilitating one-handed operation. This makes the shunt interlock system easier to use. The design features all-plastic construction with a recessed profile and plastic cover. The shunt interlock is located away from IV Pole (lower and rearward) on the side of machine. This change necessitated a modification to the IV support pole

location on the machine. There is no change in the electronic circuitry from the previously cleared 2008T hemodialysis machine.

4) Wheel Lock Pedal

The surface area of the wheel lock pedal was made larger for ease of use.

5) Reset Board

The reset board was added to the current 2008T UI-MICS (User Interface) board. The board maintains communication between 2008T touchpad and the UI-MICS board by sending a reset signal to the touchpad after every 5 seconds of inactivity (i.e., no activity on the touchpad surface, CONFIRM key or Escape key). This modification was implemented to mitigate the "missing cursor" error in the event of static discharge on the touchpad circuitry (Reference Class II recall 1225714-0126/11-001C).

M. Indications for Use

The modified Fresenius 2008T Hemodialysis Machine has the same indications for use as the unmodified device. It is indicated for acute and chronic dialysis therapy.

N. Technological Characteristics

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

A Risk Analysis has been completed and potential hazards associated with the modifications have been identified and mitigated. Mitigations have been verified wherever applicable. All potential risks were deemed acceptable after mitigation.

Performance and safety testing were conducted to ensure the safety and effectiveness of the device after the proposed modifications.

O. Performance Data

Design verification and validation testing were conducted to ensure that the modifications described in this submission did not/will not impact the essential performance of the device and function as intended.

The following tests were conducted:

6. **Touch Screen**
   - Functional Verification
   - Software Validation
   - Usability Testing

7. **Dialysate Sample Port**
   - Fluid Path Chemical Testing
   - Surface Disinfect Chemical Testing
   - Pressure Holding Testing
   - Residual Chemical Testing
   - Aging Test
   - Biocompatibility
   - Usability Testing

8. **Modified Shunt Interlock System and modified Hansen connectors**
   - Fluid Path Chemical Testing
   - Surface Disinfect Chemical Testing
   - Cycle Testing
   - Strength Testing
   - Shipping Testing
   - Safety Testing
   - Pressure Holding Testing
   - Residual Chemical Testing
   - Shunt Electrical Testing
   - Aging Test
   - Biocompatibility
   - Usability Testing

9. **Wheel Lock Pedal**
   - Cycle Testing
   - Strength Testing
   - Usability Testing
   - Safety Testing

10. Reset board

- Functional validation
- Simulated dialysis treatment
- Unstructured Testing (foreseeable misuse)
- Production Testing
- Regression Testing
- ESD

P. Conclusion

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, biocompatibility testing, risk analysis, and usability testing 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

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OCT 21 2011

Re: K111639
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: September 21, 2011
Received: September 22, 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

Indications for Use

510(k) Number (if known): K111639

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111639