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 of this 510(k) summary is provided in conformance with 21 CFR Part 807.92.

5.1 Submitter's Information

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Date of Preparation:	30 December 2011

5.2 Device Name

Trade Name:	Fresenius 2008T Hemodialysis Machine with bibag System
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

5.3 Legally Marketed Predicate Device (unmodified device)

Fresenius 2008T Hemodialysis Machine with bibag System (K101715).

5.4 Device Description

The Fresenius 2008T Hemodialysis Machine with bibag System is indicated for use in bicarbonate hemodialysis for acute and chronic renal failure.

The bibag is a specialized, single-use, sealed bag filled with USP grade dry sodium bicarbonate powder. The bibag attaches to a special connector incorporated into the front of the 2008T Hemodialysis Machine. The hemodialysis machine draws dialysis grade water into the bibag to produce a saturated solution of sodium bicarbonate online. This online generation of sodium bicarbonate can only be prepared using a specially modified Fresenius 2008T Hemodialysis Machine with bibag System and can only be used with 45x (1:44) dilution. The bibag cannot be used with other non-Fresenius hemodialysis machines capable of using cartridge type dry sodium bicarbonate because of the unique connection between the bibag disposable, the bibag connector, and the hemodialysis machine.

Modifications of the previously cleared 2008T Hemodialysis Machine with bibag system includes:

5.4.1 900g bibag Disposable:

Addition of an optional disposable 900g bibag which is equivalent to 650g bibag but increased in length to accommodate an additional 250g dry sodium bicarbonate powder. The length of a treatment session is dependent upon pre-treatment set-up time (including potential delays) and physician-prescribed dialysate flow rate and sodium bicarbonate concentration. (For example: The larger bag will provide sufficient USP grade dry sodium bicarbonate powder for 8 hours when running at a dialysate flow rate (Qd) of 500 mL/min and sodium bicarbonate concentration setting of 32 mEq/L).

There were no hardware or software changes made to the 2008T Hemodialysis Machine with bibag System to accommodate the 900g bag option. The existing bibag module attached to the machine will be used to connect the new 900g bibag with the same connector used for the 650g bibag.

Additionally, this submission includes a minor software maintenance change made to the 2008T Hemodialysis Machine with bibag System since the last clearance (K101715).

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:

5.4.2 Function (Fn) Lock Keyboard

The existing fold-down compact keyboard used on the 2008T Hemodialysis Machine (K101715) 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 higher tear resistance properties as compared to the standard silicon elastomer of the existing keyboard in the unmodified device (K101715).

Treatment modalities for the modified Fresenius 2008T Hemodialysis Machine remain identical to those for the unmodified 2008T (K101715):

> The 2008T is a high permeability hemodialysis system used for the treatment of patients with acute or chronic kidney 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.

5.5 Indications for Use

The modified Fresenius 2008T Hemodialysis Machine with bibag System has the same indications for use as the unmodified device. The Fresenius Medical Care bibag System is used with Fresenius Medical Care three stream proportioning hemodialysis systems equipped with the bibag module such as the 2008T Hemodialysis Machine and is intended

for use in bicarbonate hemodialysis for acute and chronic renal failure. The bibag system is intended for extracorporeal bicarbonate hemodialysis according to a physician's prescription.

5.6 Technological Characteristics

There are no changes in the technological characteristics of the previously cleared Fresenius 2008T Hemodialysis Machine with bibag System (K101715). The Fresenius 2008T Hemodialysis Machine with bibag system incorporates changes pertaining only to the size of the bibag disposable with 900g USP grade dry bicarbonate powder as an additional option to the previously cleared 650g bibag. There are no hardware or software changes made in the machine to accommodate this modification. The 900g bibag is designed and developed using dimensionally and functionally equivalent product specifications, construction and manufacturing methods as in the previously cleared 650g bibag (K101715). 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 and touchscreen)
- 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.

5.7 Performance Data

The performance of the modified device (900g bibag disposable and all other modifications discussed in 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 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 for the 900g bibag disposable:

- Functional Verification
- Bioburden and Endotoxin
- Shelf life
- Stability
- Unstructured testing

The following tests were conducted for the Fn Lock Keyboard:

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)

3. **Unit Testing (Fn Lock Keyboard)**

4. **Physical Testing (Fn Lock Keyboard)**
   - High Tear Elastomer: Use Life (Shelf Life)
   - High Tear Elastomer: Life cycle

5.8 Conclusion

Test results demonstrated that the modified 2008T Hemodialysis Machine with bibag System functions as intended and met pre-determined acceptance criteria. Results of functional validation, performance testing, biorburden assessment, risk analysis, safety testing, stability, shelf-life tests, and usability evaluation indicate that the modified Fresenius 2008T Hemodialysis Machine with bibag System 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

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FEB - 2 2012

Re: K120017
Trade/Device Name: 2008T Hemodialysis Machine with bibag™ System
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI, KPO
Dated: December 30, 2011
Received: January 3, 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): K120017

Device Name:

2008T Hemodialysis Machine with bibag™ System

Indications for Use:

The Fresenius bibag system is used with Fresenius three stream proportioning hemodialysis systems equipped with the bibag module such as the 2008T Hemodialysis Machine and is intended for use in bicarbonate hemodialysis for acute and chronic renal failure. The bibag is intended for extracorporeal bicarbonate hemodialysis according to a physician's prescription.

☒ 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 K120017