Fresenius Medical Care

DEC 2 1 2010

A. Submitter's Information:

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Date of Preparation:	June 16, 2010

B. Date Summary Prepared: June 16, 2010

C. Device Name:

Propriety/Trade Name:	**Fresenius 2008T Hemodialysis Machine with *bib*ag™ System**
Common/Usual Name	**Hemodialysis delivery system**
Classification Name:	**High permeability hemodialysis system**
Classification Number:	**Class II 876.5860**
Product Code/Review Panel	**KDI/Gastroenterology/Urology Panel**

C. Predicate Device Name:

- Gambro BiCart® (K013724, 1/8/02)
- Gambro BiCart® System (K873155, 10/26/87)
- Fresenius 2008T hemodialysis machine (K093902, 5/27/2010)

D. Device Description:

The Fresenius 2008T Hemodialysis Machine with bibag System is the cleared 2008T Hemodialysis Machine that has been modified to enable use of a specialized, single use, sealed bag (the "bibag") containing USP grade dry sodium bicarbonate powder to produce a saturated solution of sodium bicarbonate. The addition of the bibag system to the hemodialysis machine allows operators the option of producing a saturated sodium bicarbonate solution on-line through automated mixing of AAMI grade water and dry sodium bicarbonate powder within the bibag source disposable rather than with liquid bicarbonate concentrates. The bibag system is comprised of: (1) the bicarbonate concentrate generator (known as the bibag module); and (2) the bag of dry sodium carbonate concentrate. A specialized bibag connector [is attached? to the hemodialysis machine.] The bibag disposable hangs on two nozzles located in the bibag connector.

E. Intended 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.

F. Technological Characteristics:

The technological characteristics of the Fresenius 2008T hemodialysis machine with bibag system are equivalent to those of the BiCart, BiCart System and 2008T hemodialysis machine. Both the Fresenius 2008T hemodialysis machine with bibag system and the BiCart System prepare on-line bicarbonate from a single use dry powder container, proportion bicarbonate concentrate as part of a three stream bicarbonate proportioning system using AAMI grade water, and deliver de-aerated dialysate fluid at the desired conductivity, temperature, and specified pressure. There are no new types of safety and effectiveness questions presented by the modifications made to the 2008T hemodialysis machine to accommodate the bibag system.

G. Performance Testing:

Verification and validation testing were performed to ensure that the bibag system, including the bibag dry sodium bicarbonate (disposable), and the modified 2008T hemodialysis machine function as intended and that the modifications did not impact the essential performance of the 2008T hemodialysis machine. Testing included:

1. Full system validation and software regression testing were performed. Testing included:

    - Software validation and regression testing
    - Electromagnetic compatibility (EMC) testing
    - Electrical safety testing
    - System performance testing using bibag dry bicarbonate concentrate

    The results from the testing demonstrated that all modifications functioned as intended and met pre-determined acceptance criteria. The essential performance of the hemodialysis machine has not been impacted by the modifications.

2. Electromagnetic compatibility testing (EMC) was conducted according to the IEC 60601-1-2 (2007) Class A Testing. The modified 2008T hemodialysis machine with bibag system met the requirements of IEC 60601-1-2 (2007).

3. Electrical safety testing was conducted according to the following standards:

    - UL 60601-1, 1st Edition,2006-04-26, (Medical Electrical Equipment, Part 1:General Requirements for Safety)
    - CAN/CSA-C22.2 No. 601.1-M90, 2005, (Medical Equipment Electrical Equipment, Part 1: General Requirements for Safety)

The modified 2008T hemodialysis machine with was found to comply with the above standards.

4. Testing of the bibag disposable included:
   a) Dissolution testing per USP requirements
   b) Bioburden & Endotoxin testing per USP & AAMI RD61:2006
   c) Biocompatibility testing of the bibag materials per USP 32-NF26 biological tests <88>

H. Conclusions

The results from the testing conducted demonstrated that both the bibag system, including the bibag disposable, and the modified 2008T hemodialysis machine functioned as intended and met pre-determined acceptance criteria.

The Fresenius 2008T hemodialysis machine with bibag system was validated. The results of functional and software validation, performance testing, biocompatibility testing, risk analysis, and usability testing indicate that the Fresenius 2008T hemodialysis machine with bibag system is substantially equivalent to the named predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Randy Quinn
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WALTHAM MA 02451

DEC 2 1 2010

Re: K101715
Trade/Device Name: 2008T Hemodialysis Machine with bi*bag*™ system
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Codes: KDI and KPO
Dated: December 14, 2010
Received: December 15, 2010

Dear Mr. Quinn:

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

DEC 2 1 2010

510(k) Number (if known): K101715

Device Name: 2008T Hemodialysis Machine with bi*bag*™ system

Indications for Use:

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101715