October 27, 2022

Fresenius Medical Care Renal Therapies Group, LLC
Denise M. Oppermann
Sr. Director Regulatory Affairs
920 Winter Street
Waltham, Massachusetts 02451

Re: K222952
Trade/Device Name: 2008T BlueStar™ Hemodailysis Machine
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: September 26, 2022
Received: September 27, 2022

Dear Denise 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gema Gonzalez -S

Gema Gonzalez
Acting Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222952

Device Name
2008T BlueStar Hemodialysis Machine

Indications for Use *(Describe)*

The 2008T BlueStar Hemodialysis Machine is indicated for acute and chronic dialysis therapy in a healthcare facility. Additional therapy options for patients receiving hemodialysis include: Isolated Ultrafiltration, Sustained Low Efficiency Dialysis (SLED), and low volume hemodialysis (patients weighing ≥ 20 kg and ≤ 40 kg). This machine accommodates the use of both low flux and high flux dialyzers. The SLED therapy option is not to be used for patients weighing ≤ 40 kg. The 2008T BlueStar Hemodialysis Machine is not to be used for plasma replacement therapies, for patients weighing less than 20 kg, or for renal therapies using substitution fluid.

bibag System (Optional):

The bibag system is used with three stream proportioning Hemodialysis Machines equipped with the bibag module such as the 2008T BlueStar Hemodialysis Machine and 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.

Crit-Line Clip Monitor (CLiC) (Optional):

The Crit-Line Clip Monitor is used with the 2008T BlueStar Hemodialysis Machine to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume. The CLiC device measures hematocrit, percent change in blood volume and oxygen saturation in real time for application in the treatment of dialysis patients with the intended purpose of providing a more effective treatment for both the dialysis patient and the clinician. Based on the data that the monitor provides, the clinician/nurse, under physician direction, intervenes (i.e., increases or decreases the rate at which fluid is removed from the blood) in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common complications of dialysis which include nausea, cramping and vomiting

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 § 807.92.

5.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(781) 996-9103
Fax:	(781) 699-9635
Contact Person:	Denise Oppermann, Senior Director
Preparation Date:	9 September 2022

5.2. Device Name

Trade Name:	2008T BlueStar™ Hemodialysis Machine
Common Name:	Hemodialysis Delivery Device
Regulation Name:	High Permeability Hemodialysis System
Regulatory Class:	Class II per 21 CFR §876.5860
Product Code:	KDI
Product Code Name:	Dialyzer, high permeability with or without sealed dialysate system
FDA Review Panel:	Gastroenterology-Urology

5.3. Legally Marketed Predicate Devices

The predicate device for the 2008T BlueStar Hemodialysis Machine (hereinafter referred to as the "2008T Machine") is the 2008T BlueStar Hemodialysis Machine cleared under K173972.

5.4. Device Description

5.4.1. Device Identification

The 2008T Machines with updated hydraulics will be implemented on new 2008T Machines. The 2008T Machines are available in four (4) configurations (Table 1).

Table 1: 2008T Machine Configuration

Part Number	Description
191124	2008T HD Sys. CDX BLUESTAR
191126	2008T HD Sys. CDX W/bi*b*ag BLUESTAR
191128	2008T HD Sys. W/O CDX BLUESTAR

Part Number	Description
191130	2008T HD Sys. W/O CDX W/bi*b*ag BLUESTAR

5.4.2. Device Characteristics

The 2008T Machine is an electromechanical device. Software controls the machine during hemodialysis treatment, including fluid flow, mixing, heating, and alarms.

5.4.3. Environment of Use

The 2008T Machine is intended for use in healthcare facilities, such as hospitals and dialysis clinics where intermittent dialysis treatment is performed.

5.4.4. Brief Written Description of the Device

The 2008T Machine provides hemodialysis treatment by controlling and monitoring both the dialysate circuit and the extracorporeal blood circuit. The machine pumps blood from the patient's body through an extracorporeal circuit, one component of which is the dialyzer. The dialyzer contains a semi-permeable membrane that uses diffusion to transfer toxins and ultrafiltration to transport excess water from the blood into the dialysate circuit. In this separate dialysate circuit, the dialysate concentrates are mixed with purified water, heated, degassed, and delivered to the dialyzer through platinum cross-linked silicone tubing. Balancing chambers control the dialysate during treatment. During treatment, the extracorporeal blood circuit is monitored for venous and arterial blood pressures as well as for the presence of air and blood. The 2008T Machine accommodates the following accessory devices and options:

Accessories

- DIASAFE®*plus*US Filter (K182367)
- Patient Card (K173972)
- Patient Card Reader (K173972)
- Bloodlines: 6.35 mm and 8 mm (K962081, K000451, K001107, K022536, K070049, K120823, and K201207)
- Dialyzers: Any commercially available dialyzer equipped with ISO 8637 standard dialysis connectors
- 2008T BlueStar Hemodialysis Machine Field Upgrade Kits (K173972)

Options

- bi*b*ag® – K162716 (stand-alone disposable) and K121341 (bi*b*ag disposable cleared with 2008T HD Machine)
- CDX (Clinical Data Exchange) – K093902 (CDX cleared with 2008T HD Machine)
- CLiC (Crit-Line in a Clip Monitor) – K121599 (stand-alone CLiC) and K131908 (CLiC with 2008T HD Machine)

- BTM (Blood Temperature Monitor) – K941460 (stand-alone BTM) and K080964 (BTM with 2008T HD Machine)
- BVM (Blood Volume Monitor) – K982926 (stand-alone BVM) and K994267 (BVM with 2008K HD Machine)
- Single Needle System – K080964 (Single Needle with 2008T HD Machine)

Materials of Use

The 2008T Machine is classified as an externally communicating, blood path, indirect, prolonged contact (> 24 hours to 30 days) duration, (Category B) device in accordance with FDA guidance document *Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* (04 September 2020). A list of the hydraulic materials for the machine is provided in Table 2.

Table 2: Machine Hydraulic Materials

Component Material	Material Type
Plastic/Rubber	PPE+PS (Polyphenylene ether + polystyrene) EPDM (Ethylene propylene diene monomer rubber) PP (Polypropylene) PVDF (Polyvinylidene fluoride) PVC (Polyvinyl chloride) PPSU (Polyphenylsulfone) PESU (Polyethersulfone) PPS (Polyphenylene Sulfide) PTFE (Polytetrafluoroethylene) PEEK (Polyetheretherketone) Polyamide (glass fiber reinforced nylon) Polyester Monofilament Platinum Cross-linked Silicone
Metals	Titanium Stainless Steel Tantalum
Other	Borosilicate Glass Graphite Ceramic

5.4.5. Key Performance Specifications/Characteristic

The key performance specifications and characteristics for the 2008T Machine are outlined in Table 3.

Table 3: Key Performance Characteristics

<table>
<tr><th>Feature</th><th>Specification/Characteristic</th></tr>
<tr><td>Blood Flow Rates</td><td>
<table>
<tr><th>Blood Line</th><th>Blood Flow Rate</th></tr>
<tr><td>8 mm</td><td>20 – 600 mL/min*</td></tr>
<tr><td>6.35 (displayed as 6.4) mm</td><td>20 – 465 mL/min</td></tr>
<tr><td>4.8 mm</td><td>10 – 274 mL/min</td></tr>
<tr><td>2.6 mm</td><td>6 – 86 mL/min</td></tr>
</table>
*Not available with the Low Volume feature enabled
Accuracy: ± 10% tested at -200 mmHg
</td></tr>
<tr><td>Maximum Dialysate Flow Rate</td><td>
Dialysate flow rates are selectable on the Home screen in the following mL/min increments:
(0)/100 †‡/150†‡/200†‡/300†/400/500/600/700/800
†Sustained Low Efficiency Dialysis (SLED)
‡ Flow rate requires that the Allow Slow Flow option is selected in Service mode
The dialysate flow rates (Q_d) for both 1.5x or 2.0x dialysate flow (Auto Flow), based on the Blood Pump rate (Q_b):
<table>
<tr><th>Q_b w/1.5x Q_d (mL/min)</th><th>Q_b w/2.0x Q_d (mL/min)</th><th>Q_d (mL/min)</th></tr>
<tr><td>0 – 165*</td><td>0 – 150*</td><td>300</td></tr>
<tr><td>166 – 215*</td><td>151 – 215*</td><td>400</td></tr>
<tr><td>216 – 315*</td><td>216 – 265*</td><td>500</td></tr>
<tr><td>315 and below**</td><td>265 and below**</td><td>500</td></tr>
<tr><td>316 – 415</td><td>266 – 315</td><td>600</td></tr>
<tr><td>416 – 480</td><td>316 – 365</td><td>700</td></tr>
<tr><td>481 and above</td><td>366 and above</td><td>800</td></tr>
</table>
Note: All flow rates are approximate. Dialysate flow will not adjust unless the blood pump is adjusted at least 15 – 20 mL/min.
* If Auto Flow Minimum of 300 Q_d is set in Service mode
** If Auto Flow Minimum of 500 Q_d is set in Service mode
</td></tr>
<tr><td>Net Fluid Removal</td><td>
0 – 4000 mL/hr
<table>
<tr><th>Dialysate Flow Rate</th><th>Accuracy (on total vol. removed)</th></tr>
<tr><td>100 mL/min</td><td>± (1% UF rate + 18 mL/hr)</td></tr>
<tr><td>500 mL/min</td><td>± (1% UF rate + 30 mL/hr)</td></tr>
<tr><td>800 mL/min</td><td>± (1% UF rate + 48 mL/hr)</td></tr>
</table>
</td></tr>
</table>

Table 3: Key Performance Characteristics

Feature	Specification/Characteristic
Dialysis Time	Hemodialysis: 0 – 9:59 hours, time can be adjusted manually SLED: Fixed at 12 hours Accuracy: ± 1 second per hour
Dialysis Fluid Composition	Volumetric, selectable: Acid adjustment range: 130 – 155 mEq/L Na+ Bicarbonate adjustment range: 20 – 40 mEq/L Bicarbonate (post-reaction, after mixing with the acid and purified water) Monitoring conductivity average accuracy: ± 1.5%
Dialysis Fluid Temperature	Range 35°C – 39°C with alarm limit window automatically adjusted to 2°C above and below set point. Alarm window will not adjust to below 34°C (or 30°C during BTM recirculation measurement) or above 41°C. Accuracy: ± 0.3°C
Heparin Delivery Rate	0 – 9.9 mL/hr Accuracy: ± 5%

5.5. Intended Use

The intended use of the 2008T Machine is identical to the predicate 2008T BlueStar Hemodialysis Machine's intended use.

The 2008T Machine is intended for use in acute and chronic hemodialysis therapy.

5.6. Indications for Use

The 2008T BlueStar Hemodialysis Machine is indicated for acute and chronic dialysis therapy in a healthcare facility.

Additional therapy options for patients receiving hemodialysis include: Isolated Ultrafiltration, Sustained Low Efficiency Dialysis (SLED), and low volume hemodialysis (patients weighing ≥ 20 kg and ≤ 40 kg). This machine accommodates the use of both low flux and high flux dialyzers. The SLED therapy option is not to be used for patients weighing ≤ 40 kg. The 2008T BlueStar Hemodialysis Machine is not to be used for plasma replacement therapies, for patients weighing less than 20 kg, or for renal therapies using substitution fluid.

bi*b*ag System (Optional):

The bibag system is used with three stream proportioning Hemodialysis Machines equipped with the bibag module such as the 2008T BlueStar Hemodialysis Machine and 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.

Crit-Line Clip Monitor (CLiC) (Optional):

The Crit-Line Clip Monitor is used with the 2008T BlueStar Hemodialysis Machine to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume. The CLiC device measures hematocrit, percent change in blood volume and oxygen saturation in real time for application in the treatment of dialysis patients with the intended purpose of providing a more effective treatment for both the dialysis patient and the clinician. Based on the data that the monitor provides, the clinician/nurse, under physician direction, intervenes (i.e., increases or decreases the rate at which fluid is removed from the blood) in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common complications of dialysis which include nausea, cramping and vomiting.

5.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the 2008T Machine are substantially equivalent to those of the predicate 2008T BlueStar Hemodialysis Machine (K173872):

- Intended Use
- Indications for Use
- Design Specifications
- Technological Characteristics
- Principle of Operation
- Performance Requirements

5.8. Disinfection Testing

The 2008T Machine is provided non-sterile. The components are disinfected using either heat disinfection or chemical (bleach) disinfection using the pre-programmed machine disinfection cycle. The machine disinfection cycle has been validated to ensure an appropriate log reduction of bacteria and prevention of biofilm overgrowth in the hydraulics of the machine.

5.9. Performance Data

Performance testing to support the determination of substantial equivalence of the 2008T Machine is summarized in Table 4.

Table 4: 2008T Machine Performance Testing Summary

Test Conducted	Test Objective
Functional Tests – Long Term Aging	Verify that the machine hydraulics will not have leaks or failures after seven (7) years of aging when performing cleaning, heat disinfection, or chemical disinfection
Residual Disinfectant	Ensure that residuals from chemical disinfection are reduced to an acceptable level

Table 4: 2008T Machine Performance Testing Summary

Test Conducted	Test Objective
Inlet and Drain Hose Functional Tests	Ensure that the inlet and drain hoses can be properly connected, withstand pressure and heat, and are the proper size and color
Shunt Interlock Functional Tests	Verify that the shunt interlock performs as intended and the components do not fail or leak
Water Inlet Plate Functional Tests	Verify that the water inlet plate performs as intended and withstands expected pressures, temperatures, and chemical exposure
Disinfection Validation Testing	Ensure that the disinfection cycles preset in the machine properly reduce microorganism populations

5.9.1. Biocompatibility Testing

Biocompatibility testing for the 2008T Machine's patient contacting components was conducted in accordance with ISO 10993-1:2018 and FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" (04 September 2020). The following endpoints were evaluated to support the biological safety of the 2008T Machine:

- Cytotoxicity
- Sensitization, Guinea Pig Maximization
- Intracutaneous Irritation
- Material-Mediated Pyrogenicity
- Genotoxicity
  - Bacterial Reverse Mutation (Ames)
  - Mouse Lymphoma
- Hemocompatibility, ASTM Hemolysis (Indirect)
- Chemical Characterization
- Toxicological Risk Assessment

Human Factors Validation Testing

The changes to the hydraulics do not impact the usability of the 2008T Machine. Human Factors Validation Testing is not required to support this change to the hydraulics.

5.9.2. Electrical Safety and Electromagnetic Compatibility (EMC)

The changes to the hydraulics do not impact the electrical safety or EMC of the 2008T Machine. No new electrical safety or EMC testing is required to support the change.

5.9.3. Software Verification and Validation Testing

No software changes were made as a result of the changes to the hydraulics. No new software verification or validation testing is required to support the change.

5.9.4. Animal Studies

No animal studies were performed on the device.

5.9.5. Clinical Studies

Clinical studies were not performed on the device.

5.10. Conclusion

The Indications for Use, technological characteristics, design, and performance requirements of the 2008T BlueStar Hemodialysis Machine and its components are substantially equivalent to those of the predicate device (K173972). FMCRTG concludes that, within the meaning of the Medical Device Amendments Act of 1976, the 2008T Machine included in this submission is safe and effective for its intended use.