December 6, 2023

Fresenius Medical Care Renal Therapies Group, LLC
Denise Oppermann
Vice President - Regulatory Affairs
920 Winter Street
Waltham, Massachusetts 02451

Re: K231125
Trade/Device Name: 2008T BlueStar Hemodialysis Machine
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: November 3, 2023
Received: November 3, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Maura Rooney -S

Digitally signed by Maura Rooney -S
Date: 2023.12.06 17:56:22 -05'00'

Maura Rooney
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)*

K231125

Device Name
2008T BlueStar Hemodialysis Machine

Indications for Use *(Describe)*

2008T BlueStar Hemodialysis Machine:
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.

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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, Vice President
Preparation Date:	19 April 2023

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 Device

The 2008T BlueStar Hemodialysis Machine (K173972) is the legally marketed predicate device. This device is not currently subject to a design-related recall.

The 2008T BlueStar Hemodialysis Machine (K222952) is used as a reference device.

5.4. Device Description

5.4.1. Device Identification

The device is identified as the 2008T BlueStar Hemodialysis Machine. The software version 2.5 features will be implemented on new production 2008T BlueStar Hemodialysis Machines, 2008T BlueStar Hemodialysis Machines currently on the market, and 2008T Hemodialysis Machines currently on the market (see Table 1). Clinics will be given the option to upgrade the four (4) current 2008T Hemodialysis Machine configurations and the 4 current 2008T BlueStar Hemodialysis Machine configurations with software version 2.5 via upgrade kits.

Table 1: BlueStar Hemodialysis Machines and Field Upgrade Machines

Part Number	Part Number Description	Software Version 2.5 Features Implementation
190713	2008T Hemodialysis System with CDX	Field Upgrade
190766	2008T Hemodialysis System with bi*b*ag	
190858	2008T Hemodialysis System w/o CDX	
190895	2008T GEN2 bi*b*ag without CDX	
191124	2008T HD SYS. CDX BLUESTAR	New Production/Field Upgrade
191126	2008T HD SYS. CDX W/bi*b*ag BLUESTAR	
191128	2008T HD SYS. W/O CDX BLUESTAR	
191130	2008T HD SYS. W/O CDX W/bi*b*ag BLUESTAR	

5.4.2. Device Characteristics

The 2008T BlueStar Hemodialysis 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 BlueStar Hemodialysis 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 BlueStar Hemodialysis 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. Balancing chambers control the incoming flow and outgoing flow of the dialysate fluid during ultrafiltration. During hemodialysis, the extracorporeal blood circuit is monitored for venous and arterial blood pressures as well as for the presence of air and blood. The 2008T BlueStar Hemodialysis 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, 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)

5.4.5. Materials of Use

The 2008T BlueStar Hemodialysis Machine hydraulics assembly 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 *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 Silicone

Table 2: Machine Hydraulic Materials

Component Material	Material Type
Metals	Titanium Stainless Steel Tantalum
Other	Borosilicate Glass Graphite Ceramic

5.4.6. Key Performance Specifications/Characteristics

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

Table 3: Key Performance Characteristics

Feature	Specification/Characteristic
Blood Flow Rates	**Blood Line** / **Blood Flow Rate** 8mm / 20 – 600 mL/min* 6.35 (displayed as 6.4) mm / 20–465 mL/min 4.8 mm / 10 – 274 mL/min 2.6 mm / 6 – 86 mL/min *Not available with the Low Volume feature enabled. Accuracy: ± 10% tested at -200 mmHg

Table 3: Key Performance Characteristics

<table>
<tr><th>Feature</th><th>Specification/Characteristic</th></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.

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>
<tr><td>Dialysis Time</td><td>Hemodialysis: 0 – 9:59 hours, time can be adjusted manually
SLED: Fixed at 12 hours
Accuracy: ± 1 second per hour</td></tr>
<tr><td>Dialysis Fluid Composition</td><td>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%</td></tr>
</table>

Table 3: Key Performance Characteristics

Feature	Specification/Characteristic
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 BlueStar Hemodialysis Machine is identical to the intended use of the predicate device (K173972):

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

5.6. Indications for Use

2008T BlueStar Hemodialysis Machine: 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.

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5.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the 2008T BlueStar Hemodialysis Machine are substantially equivalent to those of the predicate 2008T BlueStar Hemodialysis Machine (K173972):

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

5.8. Performance Data

Performance testing was conducted for the 2008T BlueStar Hemodialysis Machine. Results of performance testing support substantial equivalence, safety, and efficacy of the 2008T BlueStar Hemodialysis Machine.

5.8.1. Biocompatibility Testing

In accordance with FDA guidance *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 2008T BlueStar Hemodialysis Machine hydraulics assembly is classified as an externally communicating, indirect blood contact, and prolonged exposure (> 24 hours to 30 days) Class II (Category B) device.

No changes were made to the machine's patient-contacting components. However, new blood pressure cuffs have been added to the blood pressure measurement system. Because the blood pressure cuffs are only intended to contact intact skin for transient use of blood pressure monitoring during hemodialysis treatment, they are classified as a surface, intact skin, limited contact (≤24 hr) duration, Class II (Category A) device.

The blood pressure cuffs were evaluated for biocompatibility in accordance with the requirements of:

- *ISO 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
- *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (4 September 2020)

The following endpoints were evaluated as part of the biological safety evaluation:

- Cytotoxicity
- Sensitization

- Irritation

5.8.2. Human Factors Validation Testing

Human Factors testing was performed on device modifications found to impact usability in accordance with FDA guidance *Applying Human Factors and Usability Engineering to Medical Devices* (03 February 2016). FMCRTG concludes that the new features are safe and effective for the intended users, uses, and use environments.

5.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Electromagnetic compatibility (EMC) testing was conducted on the 2008T BlueStar Hemodialysis Machine in accordance with IEC 60601-1-2:2020.

5.8.4. Software Verification and Validation Testing

Software verification testing was performed to demonstrate that the software modifications:

- Conform to user needs and intended use
- Have been implemented correctly
- Do not introduce unintended performance issues
- Are traceable to system requirements

Software verification activities were successfully completed and support the modifications described in the software version 2.5 update.

5.8.5. Animal Studies

No animal studies were performed for the 2008T BlueStar Hemodialysis Machine.

5.8.6. Clinical Studies

In accordance with *IEC 80601-2-30: Edition 2.0 2018-03 Medical electrical equipment – Part 2 – 30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers* and *ISO 81060-2 Third edition 2018-11 Non-invasive sphygmomanometers – Part 2: Clinical investigation of intermittent automated measurement type [Including: Amendment 1 (2020)]*, a clinical accuracy study was performed for the replacement blood pressure module and blood pressure cuff combination that will be incorporated with the 2008T BlueStar Hemodialysis Machine. The study concluded that the blood pressure module used in conjunction with the extension tube and blood pressure cuffs is accurate in accordance with ISO 81060-2.

5.9. Conclusion

The intended use, design, principle of operation, and technological characteristics of the 2008T BlueStar Hemodialysis Machine are substantially equivalent to those of the predicate device. Differences between the 2008T BlueStar Hemodialysis Machine and the predicate do not raise new concerns with regard to safety or efficacy. FMCRTG concludes that within the meaning of

the Medical Device Amendments Act of 1976, the 2008T BlueStar Hemodialysis Machine is safe and effective for its intended use.