May 10, 2018

Fresenius Medical Care Renal Therapies Group, LLC
Denise Oppermann
Senior Director, Regulatory Affairs
920 Winter Street
Waltham, MA 02451

Re: K173972
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: April 6, 2018
Received: April 10, 2018

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. 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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -S

for

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173972

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 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.

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.

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) 699-4479
Fax:	(781) 699-9635
Contact Person:	Denise Oppermann Senior Director, Regulatory Affairs – Devices
Preparation Date:	4 May 2018

5.2. Device Name

Trade Name:	2008T BlueStar Hemodialysis Machine
Common Name:	Dialyzer, High Permeability With or Without Sealed Dialysate System
Classification Name:	High Permeability Hemodialysis System
Regulatory Class:	Class II per 21 CFR §876.5860
Product Code	KDI
Classification Panel:	Gastroenterology/Urology

5.3. Legally Marketed Predicate Device

5.3.1. Primary Predicate – 2008K2 Hemodialysis Machine (K153449)

The 2008K2 Hemodialysis Machine (K153449) is the primary predicate for the 2008T BlueStar Hemodialysis Machine.

5.3.2. Reference Device – 2008T Hemodialysis Machine (K150708)

The 2008T Hemodialysis Machine (K150708) is the reference device for the 2008T BlueStar Hemodialysis Machine.

5.4. Device Description

5.4.1. Device Identification

The BlueStar features will be implemented on both New Production Machines and 2008T Machines currently on the market (**Table 1**). New Production 2008T BlueStar Hemodialysis

(HD) Machines will be available in four (4) configurations. Clinics will be given the option to upgrade the 4 current 2008T Hemodialysis Machine configurations with the new BlueStar software and hardware via Upgrade Kits.

Table 1: BlueStar Hemodialysis Machines and Field Upgrade Machines

Product Code	Product Code Description	BlueStar Features Implementation
190713	2008T Hemodialysis System with CDX	Field Upgrade (Standard or Premium)
190766	2008T Hemodialysis System with BIBAG	
190858	2008T Hemodialysis System w/o CDX	
190895	2008T GEN2 BIBAG without CDX	
191124	2008T HD SYS. CDX BLUESTAR	New Production
191126	2008T HD SYS. CDX W/BIBAG BLUESTAR	
191128	2008T HD SYS. W/O CDX BLUESTAR	
191130	2008T HD SYS. W/O CDX W/BIBAG BLUESTAR	

Both Standard and Premium Upgrade Kits will be offered to clinics to upgrade current 2008T Hemodialysis Machines to BlueStar software and hardware.

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 to be used in healthcare facilities.

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* Filter (K070049)
- Patient Card (subject to review in this 510(k))
- Patient Card Reader (subject to review in this 510(k))
- Bloodlines: 6.35mm and 8mm (K962081, K000451, K001107, K022536, K070049 and K120823)
- Dialyzers: Any commercially-available dialyzer equipped with ISO 8637 Standard dialysis connectors

Options

- bibag® – 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's hydraulic system is composed of the following indirect, prolonged contact, externally communicating materials:

- Plastic/Rubber:
  - PAEK (Polyaryletherketone)
  - PEI (Polyetherimide)
  - PESU (Polyethersulfone)
  - PSU (Polysulfone)
  - PET (Polyethylene terephthalate)
  - PUR (Polyurethane)
  - PET (Polyethylene terephthalate)
  - PP (Polypropylene)
  - PPO (Polyphenylene oxide)

  - PPS (Polyphenylene Sulfide)
  - PPSU (Polyphenylsulfone)
  - PTFE (Polytetrafluoroethylene)
  - PVDF (Polyvinylidene fluoride)
  - EPDM (Ethylene Propylene Diene Monomer Rubber)
  - Silicone
- Metals
  - Stainless Steel
  - Tantalum Tungsten
  - Tungsten
- Glass
  - Borosilicate Glass

The hydraulic lines of the machines are in contact with the dialysate circuit. The dialysate circuit has prolonged, indirect blood contact. Modifications have been made to components of the hydraulic system. Biocompatibility testing was conducted to verify the changes.

5.4.6. Essential Performance Characteristics

The essential performance characteristics of the 2008T BlueStar Hemodialysis Machine are listed in **Table 2**. A comparison of its essential performance characteristics with those of the 2008K2 Hemodialysis Machine (K153449) and 2008T Hemodialysis Machine (K150708) is provided in **Section 12.**

Table 2 2008T BlueStar Hemodialysis Machine Essential Performance Characteristics

<table>
<tr><th>Feature</th><th>Specification</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>Dialysate Flow Rates</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</td></tr>
</table>

<table>
<tr><th>Feature</th><th>Specification</th></tr>
<tr><td></td><td>† Sustained Low Efficiency Dialysis (SLED)
‡ Flow rate requires that the Allow Slow Flow option be selected in Service mode.

The dialysate flow rates (Qd) for both 1.5x or 2.0x dialysate flow (Auto Flow), based on the Blood Pump rate (Qb).

<table>
<tr><th>Qb w/1.5x Qd</th><th>Qb w/2.0x Qd</th><th>Qd</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 Qd is set in Service mode
** If Auto Flow Minimum of 500 Qd 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>
<table>
<tr><th>Dialysis type</th><th>Time</th></tr>
<tr><td>Dialysis</td><td>0-9:59 hours*</td></tr>
<tr><td>SLED</td><td>Fixed at 12 hours</td></tr>
</table>
*Time can be adjusted manually
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).</td></tr>
</table>

Feature	Specification
	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 BlueStar Hemodialysis Machine is identical to the primary and reference devices' intended use.

The 2008T Hemodialysis Machine is intended for acute and chronic dialysis 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 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.

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

A comparison of the technological characteristics of the 2008T BlueStar Hemodialysis Machine with the 2008K2 Hemodialysis Machine (primary predicate) and the 2008T Hemodialysis Machine (reference device) is provided in **Table 3**.

Table 3: 2008T BlueStar Hemodialysis Machine Comparison of Technological Characteristics

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
Intended Use	The device is intended for acute and chronic dialysis therapy.	The device is intended for acute and chronic dialysis therapy.	The device is intended for acute and chronic dialysis therapy.	Same
Indications for Use	2008T BlueStar Hemodialysis Machine: The 2008T BlueStar Hemodialysis Machine is indicated for acute and chronic dialysis therapy in a healthcare facility.	The 2008K2 Hemodialysis Machine is indicated for acute and chronic hemodialysis therapy in a healthcare facility.	N/A. Substantial Equivalence discussion is limited to the modified and primary predicate devices.	Same
	Additional therapy options for patients receiving hemodialysis include: Isolated Ultrafiltration, Sustained Low Efficiency Dialysis (SLED), and low volume hemodialysis (patientsweighing≥ 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.	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 2008K2 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.		Same

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
	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 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.	Bibag functionality is not available on the 2008K2 Hemodialysis Machine.		Substantially Equivalent The Indications for Use language for the optional bibag system was leveraged from the currently marketed (unmodified) 2008T Hemodialysis Machine. There were no modifications made to the optional bibag system with the 2008T BlueStar Hemodialysis Machine.
	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	Crit-Line Clip Monitor (CLiC) functionality is not available on the 2008K2 Hemodialysis Machine.		Substantially Equivalent The Indications for Use language for the optional CLiC functionality was leveraged from the currently marketed (unmodified) 2008T Hemodialysis Machine. There were no modifications made to the optional CLiC functionality with the 2008T BlueStar Hemodialysis Machine.

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
	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.			
Dimensions				
Floor Space	Approximately 54 cm wide by 63 cm deep	N/A. Substantial Equivalence discussion is limited to the modified and reference devices.	Approximately 54 cm wide by 63 cm deep	Same as the reference (unmodified) 2008T device.
Height	149 cm		149 cm	
Operating Temperature and Humidity	60°F – 100°F (15.5°C – 38°C) Relative Humidity 10% to 90%, non-condensing		60°F – 100°F (15.5°C – 38°C) Relative Humidity 10% to 90%, non-condensing	
Electrical				
Power Supply – Main	Single phase AC 117 V ± 10% 60 Hz ± 3 Hz; must be connected to a circuit which is equipped with a hospital grade receptacle and is protected by circuit breaker and ground fault interrupter (GFI). Resistance from	Single phase AC 117 V ± 10% 60 Hz ± 3 Hz; must be connected to a circuit which is equipped with a hospital grade receptacle and is protected by circuit breaker and ground fault interrupter (GFI). Resistance from	Single phase AC 117 V ± 10% 60 Hz ± 3 Hz; must be connected to a circuit which is equipped with a hospital grade receptacle and is protected by circuit breaker and ground fault interrupter (GFI). Resistance from	Same

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
	chassis to ground must be < 0.2 ohm.	chassis to ground must be < 0.2 ohm.	chassis to ground must be < 0.2 ohm.	
Power Consumption	Does not exceed 12.6 amps	Does not exceed 12.5 amps	Does not exceed 12.5 amps	Substantially Equivalent
Protection Against Electric Shock	Type: Safety class I Degree: Type B Type CF: Only BPM Blood Pressure Cuff	Type: Safety class I Degree: Type B Type CF: Only BPM Blood Pressure Cuff	Type: Safety class I Degree: Type B Type CF: Only BPM Blood Pressure Cuff	Same
Materials				
Patient-Contacting Materials	All direct and indirect patient-contacting materials have been evaluated for Biocompatibility	All direct and indirect patient-contacting materials have been evaluated for Biocompatibility	All direct and indirect patient-contacting materials have been evaluated for Biocompatibility	Same
Water				
Back Flow Prevention	Integral back flow prevention provided by external vent to atmosphere in water inlet circuit.	Integral back flow prevention provided by external vent to atmosphere in water inlet circuit.	Integral back flow prevention provided by external vent to atmosphere in water inlet circuit.	Same
Water Pressure	Min 20 psi; max 105 psi	Min 20 psi; max 105 psi	Min 20 psi; max 105 psi	Same
Water Temperature	Min 50°F (10°C); max 77°F (25°C)	Min 50°F (10°C); max 77°F (25°C)	Min 50°F (10°C); max 77°F (25°C)	Same
Water Quality	Current national (U.S.) Standards for the Quality of Water: ANSI/AAMI 13959:2014, Water for hemodialysis and related therapies ANSI/AAMI 26722:2014, Water treatment equipment	Current national (U.S.) Standards for the Quality of Water: ANSI/AAMI 13959:2014, Water for hemodialysis and related therapies ANSI/AAMI 26722:2014, Water treatment equipment	Current national (U.S.) Standards for the Quality of Water: ANSI/AAMI 13959:2014, Water for hemodialysis and related therapies ANSI/AAMI 26722:2014, Water treatment equipment	Same

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
	for hemodialysis applications and related therapies Other related standards include: ANSI/AAMI RD62:2006, Water treatment equipment for hemodialysis applications and related therapies	for hemodialysis applications and related therapies Other related standards include: ANSI/AAMI RD62:2006, Water treatment equipment for hemodialysis applications and related therapies	for hemodialysis applications and related therapies Other related standards include: ANSI/AAMI RD62:2006, Water treatment equipment for hemodialysis applications and related therapies	
Water Consumption Rate	470 mL/min, typical* *typical treatment conditions: dialysate flow rate 500 mL/min, concentrate ratio 1:44	470 mL/min, typical* *typical treatment conditions: dialysate flow rate 500 mL/min, concentrate ratio 1:44	470 mL/min, typical* *typical treatment conditions: dialysate flow rate 500 mL/min, concentrate ratio 1:44	Same
Drain	3 feet maximum height. Must comply with local codes and must maintain a free fall air gap between drain hose and building drain. 3 meters (approximately 10 feet) maximum drain hose length.	3 feet maximum height. Must comply with local codes and must maintain a free fall air gap between drain hose and building drain. 3 meters (approximately 10 feet) maximum drain hose length.	3 feet maximum height. Must comply with local codes and must maintain a free fall air gap between drain hose and building drain. 3 meters (approximately 10 feet) maximum drain hose length.	Same
Rinsing	Temperature 37°C. Flow rate 620 mL/min. Time between 10 and 60 minutes (internally selectable)	Temperature 37°C. Flow rate 620 mL/min. Time between 10 and 60 minutes (internally selectable)	Temperature 37°C. Flow rate 620 mL/min. Time between 10 and 60 minutes (internally selectable)	Same
Dialysate				
Dialysate Flow Adjustment Range	Dialysate flow rates are selectable in the following mL/min increments:	Dialysate flow rates are selectable in the following mL/min increments:	N/A. Substantial Equivalence discussion is limited to the modified and primary predicate devices.	Same

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

<table>
<tr><th>Parameter</th><th>Modified Device – 2008T BlueStar Hemodialysis Machine</th><th>Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)</th><th>Reference Device – 2008T Hemodialysis Machine (K150708)</th><th>Equivalence Discussion</th></tr>
<tr>
<td></td>
<td>(0)/100†‡/150†‡/200†‡/300†/400/500/600/700/800
† Sustained Low Efficiency Dialysis (SLED)
‡ Flow rate requires that the Allow Slow Flow option be selected in Service mode.

Dialysate flow rates (Qd) for both 1.5x or 2.0x dialysate flow (Auto Flow) based on blood flow rate (Qb)
<table>
<tr><th>Qb w/1.5x Qd</th><th>Qb w/2.0x Qd</th><th>Qd</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>
* If Auto Flow Minimum of 300 Qd is set in Service mode</td>
<td>(0)/100†‡/150†‡/200†‡/300†/400/500/600/700/800
† Sustained Low Efficiency Dialysis (SLED)
‡ Flow rate requires that the Allow Slow Flow option be selected in Service mode.

Dialysate flow rates (Qd) for both 1.5x or 2.0x dialysate flow (Auto Flow) based on blood flow rate (Qb)
<table>
<tr><th>Qb w/1.5x Qd</th><th>Qb w/2.0x Qd</th><th>Qd</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>
* If Auto Flow Minimum of 300 Qd is set in Service mode</td>
<td></td>
<td></td>
</tr>
</table>

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
	** If Auto Flow Minimum of 500 Qd is set in Service mode	** If Auto Flow Minimum of 500 Qd is set in Service mode		
Dialysate Flow Adjustment Range Accuracy	± 5%	± 5%	± 5%	Same
Concentrate Supply				
Concentrate Pressure	Max suction height 3 feet; Max supplied pressure 2 psi Note: Max supplied pressure is 10 psi with bibag kit installed.	Max suction height 3 feet; Max supplied pressure 2 psi	Max suction height 3 feet; Max supplied pressure 2 psi Note: Max supplied pressure is 10 psi with bibag kit installed.	Same as the reference (unmodified) 2008T device. Bibag functionality is not available in the primary predicate 2008K2 device.
Proportional Mixing System				
Acid	Volumetric 1:44	Volumetric, selectable 1:34 1:35.83 1:44 1:35.1	Volumetric, selectable 1:34 1:35.83 1:44 1:35.1	Substantially Equivalent. The modified device does not support the use of acetate. The remaining dialysate ratio is 1:44. The specification is revised to reflect the change.
Acetate	N/A	1:34	1:34	
Bicarbonate	Volumetric, selected with associated acid ratio 1:27.46 1:19.13 1:25.16	Volumetric, selected with associated acid ratio 1:27.46 1:19.13 1:25.16	Volumetric, selected with associated acid ratio 1:27.46 1:19.13 1:25.16	Same

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
	1:27.6	1:27.6	1:27.6	
Adjustment Range	130 – 155 mEq/L Na+ 20 – 40 mEq/L Bicarbonate (post-reaction, after mixing with acid and purified water).	130 – 155 mEq/L Na+ 20 – 40 mEq/L Bicarbonate (post-reaction, after mixing with acid and purified water).	130 – 155 mEq/L Na+ 20 – 40 mEq/L Bicarbonate (post-reaction, after mixing with acid and purified water).	Same
Optional bibag Dry Bicarbonate	Temperature-compensated conductivity display with automatically set alarm windows ± 0.5 mS/cm around calculated conductivity, limited to ± 0.4 mS/cm @ 24 mEq/L bicarbonate or less. With alarm window set at ± 0.5 mS/cm: User can move alarm window up or down an additional: ± 0.2 mS/cm @ 36 – 40 mEq/L ± 0.1 mS/cm @ 30 – 35 mEq/L no adjustment @ 20 – 29 mEq/L	N/A. Bibag functionality is not available on the 2008K2 Hemodialysis Machine	Temperature-compensated conductivity display with automatically set alarm windows ± 0.5 mS/cm around calculated conductivity, limited to ± 0.4 mS/cm @ 24 mEq/L bicarbonate or less. With alarm window set at ± 0.5 mS/cm: User can move alarm window up or down an additional: ± 0.2 mS/cm @ 40 mEq/L ± 0.1 mS/cm @ 35 mEq/L no adjustment @ 29 mEq/L	Same as the reference 2008T device. The specification is revised for clarity and remains in compliance with requirements of IEC 60601-2-16, clause 201.12.4.4.101, Composition of the DIALYSIS FLUID.
Range of Display	10.0 – 17.0 mS/cm at 25°C. Alarm limits will not go below 12.5 or above 16.0 mS/cm.	10.0 – 17.0 mS/cm at 25°C. Alarm limits will not go below 12.5 or above 16.0 mS/cm.	10.0 – 17.0 mS/cm at 25°C. Alarm limits will not go below 12.5 or above 16.0 mS/cm.	Same
Dialysate Temperature Set Range	35°C – 39°C, selectable in 0.1°C steps	35°C – 39°C, selectable in 0.1°C steps	35°C – 39°C, selectable in 0.1°C steps	Same

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
Displayed Temperature Average Accuracy	± 0.3°C	± 0.3°C	± 0.3°C	Same
Temperature Display	Range 35°C – 39°C with alarm limit window automatically adjusted to 2°C above and below set point. Alarm window will not go below 34°C (or 30°C during BTM recirculation measurement) or above 41 °C.	Range 35°C – 39°C with alarm limit window automatically adjusted to 2°C above and below set point. Alarm window will not go below 33°C (or 30 °C during BTM recirculation measurement) or above 41°C.	Range 35°C – 39°C with alarm limit window automatically adjusted to 2°C above and below set point. Alarm window will not go below 33°C (or 30 °C during BTM recirculation measurement) or above 41°C.	Substantially Equivalent Lower Dialysate Temperature Limit for non-BTM recirculation was raised from 33°C to 34°C to comply with IEC 60601-2-16:2012.
Heat Disinfection				
Temperature	83°C ± 8°C at negative temperature coefficient (NTC) 3	83°C ± 8°C at NTC 3	83°C ± 8°C at NTC 3	Same
Flow Rate	600 mL/min Pre-rinse either 10 min @ 600 mL/min or 20 min @ 300 mL/min (user selectable).	600 mL/min Pre-rinse either 7 min @ 600 mL/min or 20 min @ 300 mL/min (user selectable). 10 min @ 600 mL/min for DIASAFE PLUS equipped machines.	600 mL/min Pre-rinse either 7 min @ 600 mL/min or 20 min @ 300 mL/min (user selectable). 10 min @ 600 mL/min for DIASAFE PLUS equipped machines.	Substantially Equivalent In the modified device, DIASAFE PLUS is standard. The specification is revised accordingly.
Time	Between 10 and 60 minutes (internally selectable)	Between 10 and 60 minutes (internally selectable)	Between 10 and 60 minutes (internally selectable)	Same
Auto Heat Disinfect Pre-Rinse Time	Between 15 and 30 minutes (user selectable) @ 600 mL/min (standard) or 350 mL/min (extended pre-rinse). Note: Heater is off during pre-rinse.	Between 15 and 30 minutes (user selectable) @ 600 mL/min (standard) or 350 mL/min (extended pre-rinse). Note: Heater is off during pre-rinse.	Between 15 and 30 minutes (user selectable) @ 600 mL/min (standard) or 350 mL/min (extended pre-rinse). Note: Heater is off during pre-rinse.	Same

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
Auto Heat Disinfect Pressure	25 psi < pressure < 90 psi	25 psi < pressure < 90 psi	25 psi < pressure < 90 psi	Same
Chemical Disinfection				
Temperature	37°C (set point applicable)	37°C (set point applicable)	37°C (set point applicable)	Same
Flow Rate	620 mL/min	620 mL/min	620 mL/min	Same
Time	Between 10 and 60 minutes (internally selectable)	Between 10 and 60 minutes (internally selectable)	Between 10 and 60 minutes (internally selectable)	Same
Blood Pump				
Blood Flow Rates	Blood line: 8 mm; 6.35 (displayed as 6.4) mm; 4.8 mm; 2.6 mm Blood flow rate: 20–600 mL/min; 20–465 mL/min; 10–274 mL/min; 6–86 mL/min	Blood line: 8 mm; 6.35 (displayed as 6.4) mm; 4.8 mm; 2.6 mm Blood flow rate: 20–600 mL/min; 20–465 mL/min; 10–274 mL/min; 6–86 mL/min	Blood line: 8 mm; 6.35 (displayed as 6.4) mm; 4.8 mm; 2.6 mm Blood flow rate: 20–600 mL/min; 20–465 mL/min; 10–274 mL/min; 6–86 mL/min	Same
Blood Flow Rate Accuracy	± 10% tested at -200 mmHg	± 10% tested at -200 mmHg	N/A. Substantial Equivalence discussion is limited to the modified and primary predicate devices.	Same
Level Adjust	Up Only	Up Only	Up Only	Same
Power Outage Use	The pump can be manually operated with a hand crank.	The pump can be manually operated with a hand crank.	The pump can be manually operated with a hand crank.	Same
Single Needle System				

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
Two Pump Procedure	With two blood pumps, pressure control system with alternating blood pumps. Alarm after 15 or 30 seconds without an alternation of the pumps.	With two blood pumps, pressure control system with alternating blood pumps. Alarm after 15 or 30 seconds without an alternation of the pumps.	With two blood pumps, pressure control system with alternating blood pumps. Alarm after 15 or 30 seconds without an alternation of the pumps.	Same
Heparin Pump				
Administration Rate	0 – 9.9 mL/hr Accuracy: ± 5%	0 – 9.9 mL/hr Accuracy: ± 5%	0 – 9.9 mL/hr Accuracy: ± 5%	Same
Monitoring	Monitoring end of stroke	Monitoring end of stroke	Monitoring end of stroke	Same
Bolus	From 0.1 mL – 9.9 mL volume	From 0.1 mL – 9.9 mL volume	From 0.1 mL – 9.9 mL volume	Same
Type of Syringe	10 mL – 12 mL disposable syringes The syringes are identified with the Vendor Syringe Name and Vendor Code. BD 10 mL Syringe Only, 301997 BD 10 mL Safety-Lok, 305564 BD 10 mL Luer-Lok with Needle, 309642 BD 10 mL Syringe & Needle Combo (WWD-Mexico), 309642-20 BD 10 mL Luer-Lok, 309604 10 mL BD Luer-Lok with 20 G x 1 in. needle, 309644	10 mL – 12 mL disposable syringes The syringes are identified with the Vendor Syringe Name and Vendor Code. BD 10 mL Syringe Only, 301997 BD 10 mL Safety-Lok, 305564 BD 10 mL Luer-Lok with Needle, 309642 BD 10 mL Syringe & Needle Combo (WWD-Mexico), 309642-20 BD 10 mL Luer-Lok, 309604 10 mL BD Luer-Lok with 20 G x 1 in. needle, 309644	N/A. Substantial Equivalence discussion is limited to the modified and primary predicate devices.	Same Additional heparin syringes, initially reviewed and cleared with the predicate 2008K2, have been validated for use on the modified 2008T machine's heparin pump (Section 18).

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
	Covidien/Kendall Monoject 12 mL Luer-Lock (relabeled as 10 mL), 1181200777T Covidien/Kendall Monoject 12 cc Luer Lock, 1181200777 Terumo 10 cc Luer Lock Tip Syringe without Needle, SS-10L B. Braun 10 mL Injekt Luer-Lock, 4606728V-02 B. Braun 10 mL Luer-Lock, 4617100V-02 Nipro 10 cc Luer-Lock without needle, JD+10L-WEI Nipro 10 cc Luer-Lock, JD+10L2025-WEI Sol-Care 10 mL Luer-Lock Safety Syringe without Needle, 120008IM SOL-M 10 mL Luer Lock Syringe without Needle, 180010	Covidien/Kendall Monoject 12 mL Luer-Lock (relabeled as 10 mL), 1181200777T Covidien/Kendall Monoject 12 cc Luer Lock, 1181200777 Terumo 10 cc Luer Lock Tip Syringe without Needle, SS-10L B. Braun 10 mL Injekt Luer-Lock, 4606728V-02 B. Braun 10 mL Luer-Lock, 4617100V-02 Nipro 10 cc Luer-Lock without needle, JD+10L-WEI Nipro 10 cc Luer-Lock, JD+10L2025-WEI Sol-Care 10 mL Luer-Lock Safety Syringe without Needle, 120008IM SOL-M 10 mL Luer Lock Syringe without Needle, 180010		
Monitoring Elements: Blood Circuit				
Arterial Pressure Monitor (Standard)	-300 mmHg to +500 mmHg with 3 automatically set time-delayed alarm window limit values (± 60 mmHg, ± 80 mmHg, and ± 100 mmHg of actual pressure (Single Needle ± 80 mmHg)).	-300 mmHg to +500 mmHg with 3 automatically set time-delayed alarm window limit values (± 60 mmHg, ± 80 mmHg, and ± 100 mmHg of actual pressure (Single Needle ± 80 mmHg)).	-300 mmHg to +500 mmHg with 3 automatically set time-delayed alarm window limit values (± 60 mmHg, ± 80 mmHg, and ± 100 mmHg of actual pressure (Single Needle ± 80 mmHg)).	Same
Venous Pressure Monitor (Standard)	-80 mmHg to +500 mmHg with 3 fixed window limit	-80 mmHg to +500 mmHg with 3 fixed window limit	-80 mmHg to +500 mmHg with 3 fixed window limit	Same

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
	values of ± 60 mmHg, ± 80 mmHg, and ± 100 mmHg of actual pressure. There is also an asymmetric range initially set to ± 80 mmHg which increases the lower limit after 60 seconds (Single Needle ± 80 mmHg).	values of ± 60 mmHg, ± 80 mmHg, and ± 100 mmHg of actual pressure. There is also an asymmetric range initially set to ± 80 mmHg which increases the lower limit after 60 seconds (Single Needle ± 80 mmHg).	values of ± 60 mmHg, ± 80 mmHg, and ± 100 mmHg of actual pressure. There is also an asymmetric range initially set to ± 80 mmHg which increases the lower limit after 60 seconds (Single Needle ± 80 mmHg).	
Accuracy	± 20 mmHg or ± 10% of indicated reading, whichever is greater	± 20 mmHg or ± 10% of indicated reading, whichever is greater	± 20 mmHg or ± 10% of indicated reading, whichever is greater	Same
TMP Monitor	+60 mmHg to -520 mmHg with automatically set time-delayed window limit values of ± 60 mmHg (conventional dialysis) and ± 40 mmHg (high flux dialysis). Compensation for upward drift.	+60 mmHg to -520 mmHg with automatically set time-delayed window limit values of ± 60 mmHg (conventional dialysis) and ± 40 mmHg (high flux dialysis). Compensation for upward drift.	+60 mmHg to -520 mmHg with automatically set time-delayed window limit values of ± 60 mmHg (conventional dialysis) and ± 40 mmHg (high flux dialysis). Compensation for upward drift.	Same
Level Detector	Ultrasonic impulses detect fluid level in the drip chamber.	Ultrasonic impulses detect fluid level in the drip chamber.	Ultrasonic impulses detect fluid level in the drip chamber.	Same
Optical Sensor	Optical transmission used to detect opaque or non-opaque fluid presence in the blood tubing.	Optical transmission used to detect opaque or non-opaque fluid presence in the blood tubing.	Optical transmission used to detect opaque or non-opaque fluid presence in the blood tubing.	Same
Clamp	Closes with any blood alarm	Closes with any blood alarm	Closes with any blood alarm	Same
Level Adjust	Allows the level in the drip chamber to rise to maintain the desired fluid level in the drip chamber	Allows the level in the drip chamber to rise to maintain the desired fluid level in the drip chamber	Allows the level in the drip chamber to rise to maintain the desired fluid level in the drip chamber	Same

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
Blood Pump speed and direction monitors	Optical speed tachometer, Hall-effect direction sensor Alarm Limits: 30 second delay, maximum	Optical speed tachometer, Hall-effect direction sensor Alarm Limits: 30 second delay, maximum	Optical speed tachometer, Hall-effect direction sensor Alarm Limits: 30 second delay, maximum	Same
Blood Leak Detector	Two color light source transmitter/sensor Resolution: minor ≥ 0.35 mL/min of blood (hematocrit = 25%) alarm ≥ 0.45 mL/min of blood (hematocrit = 25%)	Two color light source transmitter/sensor Resolution: minor ≥ 0.35 mL/min of blood (hematocrit = 25%) alarm ≥ 0.45 mL/min of blood (hematocrit = 25%)	Two color light source transmitter/sensor Resolution: minor ≥ 0.35 mL/min of blood (hematocrit = 25%) alarm ≥ 0.45 mL/min of blood (hematocrit = 25%)	Same
Ultrafiltration Control				
UF Pump Volume Accuracy	± 1% (for P_{di} > -500 mbar) where P_{di} = dialysate pressure on the inlet side of the dialyzer	± 1% (for P_{di} > -500 mbar) where P_{di} = dialysate pressure on the inlet side of the dialyzer	± 1% (for P_{di} > -500 mbar) where P_{di} = dialysate pressure on the inlet side of the dialyzer	Same
Fluid Removal Rate from Patient	0 – 4000 mL/hr Dialysate flow rate at 100 mL/min: Accuracy (on total volume removed): ± (1% UF rate + 18 mL/hr) Dialysate flow rate at 500 mL/min: Accuracy (on total volume removed): ± (1% UF rate + 30 mL/hr) Dialysate flow rate at 800 mL/min: Accuracy (on total volume removed): ± (1% UF rate + 48 mL/hr)	0 – 4000 mL/hr Dialysate flow rate at 100 mL/min: Accuracy (on total volume removed): ± (1% UF rate + 18 mL/hr) Dialysate flow rate at 500 mL/min: Accuracy (on total volume removed): ± (1% UF rate + 30 mL/hr) Dialysate flow rate at 800 mL/min: Accuracy (on total volume removed): ± (1% UF rate + 48 mL/hr)	0 – 4000 mL/hr Dialysate flow rate at 100 mL/min: Accuracy (on total volume removed): ± (1% UF rate + 18 mL/hr) Dialysate flow rate at 500 mL/min: Accuracy (on total volume removed): ± (1% UF rate + 30 mL/hr) Dialysate flow rate at 800 mL/min: Accuracy (on total volume removed): ± (1% UF rate + 48 mL/hr)	Same
Adjustment Range of UF Rate (Dialysis)	Volumetric Control, Adjusted in 10 mL increments.	Volumetric Control, Adjusted in 10 mL increments.	Volumetric Control, Adjusted in 10 mL increments.	Same

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
	Dialysis: 0 – 4000 mL/hr Dialysis settings: 1000 mL/hr, 2000 mL/hr, 3000 mL/hr, and 4000 mL/hr	Dialysis: 0 – 4000 mL/hr Dialysis settings: 1000 mL/hr, 2000 mL/hr, 3000 mL/hr, and 4000 mL/hr	Dialysis: 0 – 4000 mL/hr Dialysis settings: 1000 mL/hr, 2000 mL/hr, 3000 mL/hr, and 4000 mL/hr	
UF Time	Digital Display (0 – 9:59 hrs), selectable in increments of 1 min	Digital Display (0 – 9:59 hrs), selectable in increments of 1 min	Digital Display (0 – 9:59 hrs), selectable in increments of 1 min	Same
UF Goal	Digital Display (0 – 9,990 mL), selectable in increments of 10 mL	Digital Display (0 – 9,990 mL), selectable in increments of 10 mL	Digital Display (0 – 9,990 mL), selectable in increments of 10 mL	Same
UF Profiles	Eight UF profiles are available for the removal of fluid from the patient. Four are preset and four may be defined by the user.	Eight UF profiles are available for the removal of fluid from the patient. Four are preset and four may be defined by the user.	Eight UF profiles are available for the removal of fluid from the patient. Four are preset and four may be defined by the user.	Same
Remaining Time of Dialysis (RTD)	0 – 9:59 hours auto transfer from UF time, counting down in 1-minute increments. Can adjust manually.	0 – 9:59 hours auto transfer from UF time, counting down in 1-minute increments. Can adjust manually.	0 – 9:59 hours auto transfer from UF time, counting down in 1-minute increments. Can adjust manually.	Same
UF Removed Display	Digital display max 9,999 mL counting in 1 mL increments.	Digital display max 9,999 mL counting in 1 mL increments.	Digital display max 9,999 mL counting in 1 mL increments.	Same
Fluid Removal Rate Monitoring	Alarm Limit: 300 mL/hr minimum (Diasafe Plus installed) Online Pressure Holding test for hydraulic leak detection (detects leaks in the system greater than 300 mL/hr)	Alarm Limit: 300 mL/hr minimum (Diasafe Plus installed) Online Pressure Holding test for hydraulic leak detection (detects leaks in the system greater than 300 mL/hr)	Alarm Limit: 300 mL/hr minimum (Diasafe Plus installed) Online Pressure Holding test for hydraulic leak detection (detects leaks in the system greater than 300 mL/hr)	Same

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
Additional Monitoring	Alarm in case of power failure. Alarm in case of water shortage.	Alarm in case of power failure. Alarm in case of water shortage.	Alarm in case of power failure. Alarm in case of water shortage.	Same
Functional Options				
Access Flow (Qa) (Optional, requires Online Clearance (OLC))	Minimum Qa: Will not determine the Qa if less than the blood pump speed. Maximum Qa: 2000 mL/min	Minimum Qa: Will not determine the Qa if less than the blood pump speed. Maximum Qa: 2000 mL/min	Minimum Qa: Will not determine the Qa if less than the blood pump speed. Maximum Qa: 2000 mL/min	Same
Online Clearance (Optional)	Dialysate Flow rate: 300 mL/min – 800 mL/min # of online clearance tests: 1 – 6 during each treatment	Dialysate Flow rate: 300 mL/min – 800 mL/min # of online clearance tests: 1 – 6 during each treatment	Dialysate Flow rate: 300 mL/min – 800 mL/min # of online clearance tests: 1 – 6 during each treatment	Same
SLED Discussion: **The SLED functionality, reviewed and cleared with the 2008K2 Hemodialysis machine (K153449), is being implemented in the modified 2008T Bluestar Hemodialysis machine. Implementation of SLED in the modified device is identical to the predicate 2008K2 Hemodialysis machine. As with the 2008K2 device, "SLED" is a selectable treatment option on 'Select Program' screen. The labeling of the modified device reflects that the SLED functionality is contraindicated in patients weighing ≤ 40 kg.**				
Dialysate Flow Rates	100 mL/min, 150 mL/min, 200 mL/min, and 300 mL/min	100 mL/min, 150 mL/min, 200 mL/min, and 300 mL/min	N/A. Substantial Equivalence discussion is limited to the modified and primary predicate devices.	Same
Ultrafiltration Rate	Volumetric Control, adjusted in 10 mL/hr increments. 0 – 1000 mL/hr	Volumetric Control, adjusted in 10 mL/hr increments. 0 – 1000 mL/hr		Same
Blood Flow Rates	0 – 300 mL/min	0 – 300 mL/min		Same
Treatment Time	0 – 12:00 (hours : minutes)	0 – 12:00 (hours : minutes)		Same

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
Low Volume Hemodialysis Discussion: **Restricts the allowable blood pump segment sizes to less than to 6.4 mm for patients weighing between 20 kg and 40 kg. Reviewed and cleared with the 2008K2 Hemodialysis machine (K153449), and is being implemented in the modified 2008T Bluestar Hemodialysis machine. The Low Volume functionality in the modified device is identical to the feature in the predicate 2008K2 device.**				
Ultrafiltration Rate	Volumetric Control, adjusted in 10 mL/hr increments. 0 – 1000 mL/hr	Volumetric Control, adjusted in 10 mL/hr increments. 0 – 1000 mL/hr	N/A. Substantial Equivalence discussion is limited to the modified and primary predicate devices.	Same
Blood Flow Rate	6 mL/min – 465 mL/min, depending on pump segment ID: 2.6 mm: 6 mL/min – 86 mL/min 4.8 mm: 10 mL/min – 274 mL/min 6.35 mm: 20 mL/min – 465 mL/min	6 mL/min – 465 mL/min, depending on pump segment ID: 2.6 mm: 6 mL/min – 86 mL/min 4.8 mm: 10 mL/min – 274 mL/min 6.35 mm: 20 mL/min – 465 mL/min		Same
Inner Diameter (ID) of pump segment	< 6.4 mm	< 6.4 mm		Same
Machine Alarm	A visual and audible indication to Operator will occur when the blood pump segment internal diameter of greater than 6.4 mm is used and Low Volume is set to On.	A visual and audible indication to Operator will occur when the blood pump segment internal diameter of greater than 6.4 mm is used and Low Volume is set to On.		Same

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
Venous Pressure Monitor	Low Volume: -60 mmHg to +300 mmHg with 3 fixed window limit values of ± 40 mmHg, ± 60 mmHg, and ± 80 mmHg of set pressure. (Single Needle ± 80 mmHg).	Low Volume: -60 mmHg to +300 mmHg with 3 fixed window limit values of ± 40 mmHg, ± 60 mmHg, and ± 80 mmHg of set pressure. (Single Needle ± 80 mmHg).		Same
Arterial Pressure Monitor	-260 mmHg to +100 mmHg (Pre Blood Pump) or -60 mmHg to +300 mmHg (Post Blood Pump) with 3 automatically set alarm limit window widths (± 40, ± 60, and ± 80) mmHg centered around set pressure. (Single Needle ± 80 mmHg).	-260 mmHg to +100 mmHg (Pre Blood Pump) or -60 mmHg to +300 mmHg (Post Blood Pump) with 3 automatically set alarm limit window widths (± 40, ± 60, and ± 80) mmHg centered around set pressure. (Single Needle ± 80 mmHg).		Same
Technique	Measures systolic, diastolic pressures, and heart rate (pulse rate) using oscillometric method. MAP measured.	Measures systolic, diastolic pressures, and heart rate (pulse rate) using oscillometric method. MAP measured.	N/A. Substantial Equivalence discussion is limited to the modified and primary predicate devices.	Same
Cuff Deflation	Interactive computer controlled. Determination for standard patients requires approximately 25 – 30 seconds depending on starting point, heart rate, and motion artifact.	Interactive computer controlled. Determination for standard patients requires approximately 25 – 30 seconds depending on starting point, heart rate, and motion artifact.		Same
Cuff Inflation	Typically 5 – 10 seconds from 0 – 250 mmHg	Typically 5 – 10 seconds from 0 – 250 mmHg		Same

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
Interval Settings	Interval times: 5 – 60 minutes in increments of 5 minutes Clock Time: 5, 10, 15, 20, 30, 60 minutes	Interval times: 5 – 60 minutes in increments of 5 minutes Clock Time: 5, 10, 15, 20, 30, 60 minutes		Same
Blood Pressure Module Performance limits for Standard therapy (> 40 kg)	Cuff Pressure Range: 0 – 300 mmHg Initial Cuff Inflation: 180 mmHg or adjusted by host Systolic Determination Range: 60 – 250 mmHg MAP Determination Range: 45 – 220 mmHg Diastolic Determination Range: 40 – 200 mmHg Pulse Rate Determination Range: 40 – 200 BPM Cuff Inflation Rate: 5 seconds Determination Time Normal: 25 – 30 seconds Overpressure Cut Off: 300 mmHg Transducer Drift: Auto Zeroing Leakage Rate (Max): 3 mmHg/min in 3 minutes Pressure Rate Offset: Auto Zeroing	Cuff Pressure Range: 0 – 300 mmHg Initial Cuff Inflation: 180 mmHg or adjusted by host Systolic Determination Range: 60 – 250 mmHg MAP Determination Range: 45 – 220 mmHg Diastolic Determination Range: 40 – 200 mmHg Pulse Rate Determination Range: 40 – 200 BPM Cuff Inflation Rate: 5 seconds Determination Time Normal: 25 – 30 seconds Overpressure Cut Off: 300 mmHg Transducer Drift: Auto Zeroing Leakage Rate (Max): 3 mmHg/min in 3 minutes Pressure Rate Offset: Auto Zeroing		Same

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine		Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)		Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
Alarm Preset Values for Standard Therapy (> 40 kg)	Systolic	200/90	Systolic	200/90		Same
	MAP	120/70	MAP	120/70		
	Diastolic	110/50	Diastolic	110/50		
	Pulse	120/50	Pulse	120/50		
	Inflation Pressure	Auto	Inflation Pressure	Auto		
Blood Pressure Module Performance limits for Low Volume therapy (20 kg – 40 kg)	Cuff Pressure Range	0 – 210 mmHg	Cuff Pressure Range	0 – 210 mmHg		Same
	Initial Cuff Inflation	120 mmHg or adjusted by host	Initial Cuff Inflation	120 mmHg or adjusted by host		
	Systolic Determination Range	60 – 220 mmHg	Systolic Determination Range	60 – 220 mmHg		
	MAP Determination Range	45 – 220 mmHg	MAP Determination Range	45 – 220 mmHg		
	Diastolic Determination Range	40 – 200 mmHg	Diastolic Determination Range	40 – 200 mmHg		
	Pulse Rate Determination Range	40 – 200 BPM	Pulse Rate Determination Range	40 – 200 BPM		
	Cuff Inflation Rate	5 seconds	Cuff Inflation Rate	5 seconds		
	Determination Time Normal	Approx. 20 seconds	Determination Time Normal	Approx. 20 seconds		
	Overpressure Cut Off	210 mmHg	Overpressure Cut Off	210 mmHg		
	Transducer Drift	Auto Zeroing	Transducer Drift	Auto Zeroing		
	Leakage Rate (Max)	3 mmHg/min in 3 minutes	Leakage Rate (Max)	3 mmHg/min in 3 minutes		

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
	Pressure Rate Offset: Auto Zeroing	Pressure Rate Offset: Auto Zeroing		
Alarm Preset Values for Low Volume Therapy (20 kg – 40 kg)	Systolic: 160/80 MAP: 120/60 Diastolic: 100/40 Pulse: 120/50 Inflation Pressure: Auto	Systolic: 160/80 MAP: 120/60 Diastolic: 100/40 Pulse: 120/50 Inflation Pressure: Auto		Same
Priming the Blood Circuit				
Priming Method	Available methods enable the removal of air from the blood lines and dialyzer by allowing the sterile saline solution to flow through them.	Available methods enable the removal of air from the blood lines and dialyzer by allowing the sterile saline solution to flow through them.	Available methods enable the removal of air from the blood lines and dialyzer by allowing the sterile saline solution to flow through them.	Same
Reinfusion				
Reinfusion Method	Assisted Reinfusion. Assists the operator in returning all the patient's blood at the end of treatment. Button displayed on 'Test & Options' screen	Unassisted Reinfusion.	Unassisted Reinfusion.	Substantially Equivalent. All devices provide a means for returning blood to the patient after treatment. The proposed device introduces a new mechanism of returning blood.
Conductivity Testing				
Monitoring	Temperature compensated electronic conductivity meter with adjustable alarm limits.	Temperature compensated electronic conductivity meter with adjustable alarm limits.	Temperature compensated electronic conductivity meter with adjustable alarm limits.	Same

FRESENIUS MEDICAL CARE

2008T BlueStar Hemodialysis Machine
Traditional 510(k)

Parameter	Modified Device – 2008T BlueStar Hemodialysis Machine	Primary Predicate Device – 2008K2 Hemodialysis Machine (K153449)	Reference Device – 2008T Hemodialysis Machine (K150708)	Equivalence Discussion
	Temperature-compensated conductivity display with automatically set alarm windows ± 0.5 mS/cm around calculated conductivity. User can adjust an additional ± 0.5 mS/cm within this range. Average Accuracy: ± 1.5%	Temperature-compensated conductivity display with automatically set alarm windows ± 0.5 mS/cm around calculated conductivity. User can adjust an additional ± 0.5 mS/cm within this range. Average Accuracy: ± 1.5%	Temperature-compensated conductivity display with automatically set alarm windows ± 0.5 mS/cm around calculated conductivity. User can adjust an additional ± 0.5 mS/cm within this range. Average Accuracy: ± 1.5%	
Conductivity Testing Method	Independent Conductivity. Reading displayed on 'Dialysate' screen when the dialysate lines are on the shunt interlock	Manual. Operator tests for proper conductivity before each dialysis treatment	Manual. Operator tests for proper conductivity before each dialysis treatment	Substantially Equivalent. All devices provide a means for conductivity testing. The proposed device introduces a new mechanism of measuring conductivity.

5.8. Performance Data

The performance of the modified device described in this submission was evaluated according to existing FMCRTG procedures, protocols, declared performance standards, and guidelines of the quality system regulation (21 CFR §820). Design verification tests confirmed that all design updates were effective, did not affect the essential performance of the device, and that the device functions as intended.

5.8.1. Biocompatibility Testing

The 2008T BlueStar Hemodialysis Machine's hydraulic components were evaluated to ISO 10993 requirements. The Unit Under Test (UUT) included the new hardware components (acid, bicarbonate and UF pumps, extended concentrate lines and ratio valves). The following testing was performed to support the biological safety of the 2008T BlueStar HD Machine's hydraulics:

- Chemical analysis – Simulated-Use Leachable Extraction
- Cytotoxicity
- Sensitization
- Irritation
- Material Mediated Pyrogenicity
- Hemocompatibility (Indirect Contact)
- Subchronic toxicity
- Risk assessment of potential toxicity

5.8.2. Electrical Safety and Electromagnetic Compatibility (EMC)

The 2008T BlueStar Hemodialysis Machine was evaluated for electromagnetic compatibility (EMC) in accordance with IEC 60601-1-2:2014. Additional electrical testing was conducted to verify new BlueStar hardware.

5.8.3. Software Verification and Validation Testing

Unit, integration, and system level software verification testing was performed to demonstrate the effectiveness of the software modifications and to confirm operation of the machine.

The following system level testing was performed:

- Functional and performance verification testing – conducted to ensure operational efficacy of software with the upgraded hardware
- Regression testing – conducted on dialysis treatment and key safety measures to ensure the essential performance and safe operation of the system were not adversely impacted

Code reviews were performed for all changes to the code. To ensure that the inputs were met and good coding practices were followed, the code reviews analyzed the following source documents:

- Design inputs
- Software Design Specification (SDS)
- "diff files"

5.8.4. Mechanical Testing

Functional verification of mechanical components was conducted to verify the following changes:

- New paint
- Tubing organizer
- Patient Card housing
- Keyboard
- Monitor EMI ground assembly
- Hook for extended lines
- Ratio valves
- UF pumps, acid and bicarbonate pumps

5.8.5. Environmental and Ship Testing

Environmental testing was performed to verify that the machine performs normally (i.e., no non-resettable alarms or unusual behavior) in the temperature- and humidity-controlled operating environment.

Ship testing was performed to verify that the machine can withstand hazards associated with the typical shipping and distribution environment. A series of reliability tests were conducted to show that the product met shipping requirements.

5.8.6. Human Factors Testing

Human Factors testing was performed on device modifications found to impact usability. FMCRTG concludes that the new features are safe and effective for the intended users, uses, and use environments.

5.9. Conclusions

The 2008T BlueStar Hemodialysis Machine's indications for use, intended use, and technological characteristics are equivalent to those of the primary predicate and reference devices. Differences between the 2008T BlueStar Hemodialysis Machine and the predicate and reference devices do not raise any new concerns with regard to safety or effectiveness. FMCRTG concludes that the proposed 2008T

BlueStar Hemodialysis Machine is substantially equivalent to the predicate device, the 2008K2 Hemodialysis Machine (K153449) within the meaning of the Medical Device Amendments Act of 1976.