The 2008T BlueStar™ Hemodialysis Machine – Special 510(k) Notification

Course: RGA 6202: Medical Device Development: A Regulatory Overview

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A. Cover letter

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920 Winter Street
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U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Re: Special 510(k) Submission for 2008T BlueStarTM Hemodialysis Machine

To Whom It May Concern,
Fresenius Medical Care Renal Therapies Group is submitting this Special 510(k) Premarket Notification LLC, for modifications to the 2008T BlueStarTM Hemodialysis Machine, a Class II device regulated under 21 CFR §876.5860, with the product code KDI.

The modifications to the 2008T BlueStarTM Hemodialysis Machine include the addition of features such as the Heparin and Sodium Variation System (SVS) Status, Dialysate Flow Button, Applications Installed - Display, Configurator, and Sodium Variation System (SVS) as an Optional Feature. Additionally, a wireless adapter has been added. The 2008T BlueStar Hemodialysis Machine is indicated for acute and chronic dialysis therapy. The technological characteristics, performance data, and safety features of the modified device remain consistent with the unmodified device.

The modified 2008T BlueStar Hemodialysis Machine has undergone rigorous testing, including software verification and validation, safety systems verification, simulated dialysis treatment, production test procedure, unstructured and static code verification. Test results demonstrate that the modified device functions as intended and meets pre-determined acceptance criteria.

The modified 2008T BlueStar Hemodialysis Machine is substantially equivalent to the legally marketed predicate device, and the modifications do not impact the safety and effectiveness of the device for its intended use. A risk analysis has been conducted, potential hazards identified, and mitigations implemented.

Enclosed are two copies of the Special 510(k) submission, including the original signed FDA Form 3674, Declaration of Conformity and Summary Reports, Truthful and Accurate Statement, and Software Development Certification, in both paper and electronic formats.

We appreciate the FDA's consideration of this Premarket Notification. Should you require any additional information regarding this submission, please contact me at the e-mail or telephone number indicated below.
Grad Student
Regulatory Technical Specialist

B. 510(k) Summary

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR Part 807.92.

C. Submitters Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, Massachusetts 02451
Phone:	(781) 699-4479
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Contact Person:	Denise Oppermann, Senior Director Regulatory Affairs - Devices Renal Therapies Group
Date of Preparation:	22 November 2023

D. Device Name

Trade Name:	2008T BlueStar^{TM} 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

E. Legally Marketed Predicate Device (Unmodified Device)

2008T BlueStarTM Hemodialysis Machine (K222952)

F. Device Description:

The 2008T BlueStar Hemodialysis Machine (K222952) 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 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) 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.

G. Modifications

Modifications to the previously cleared 2008T BlueStar Hemodialysis include:

Heparin and Sodium Variation System (SVS) Status: Addition of visual indication (display) on the home screen and dialysate screen.

Dialysate Flow Button: Addition of Dialysate Flow ON-OFF button in the Dialysate Screen.

Applications Installed - Display: Addition of text identifying which applications (Apps) have been loaded is added to the machine's opening screen.

Configurator: Software modification to support the transfer of machine configuration information between machines during installation or upgrade in service mode.

Sodium Variation System (SVS) as an Optional Feature: Addition of SVS selection in service mode to make the existing SVS feature optional.

The following modification was implemented following a regulatory assessment that the change did not affect the fundamental scientific technology or intended use of the device. Based on FDA guidance "Deciding When to Submit a.510(k) for a Change to an Existing Device", Fresenius Medical Care North America determined that this modification did not necessitate a516(k) submission:

Wireless Adapter: Adual band (i.e. 2.5Ghz and 5Ghz) wireless adapter provides the wireless network link for the CDX PC, and supports 802.lla/b/g/n. This new wireless adapter replaces the obsolete wireless adapter (unmodified device) and maintains the latest wireless technology.

H. Indications for Use

The 2008T BlueStar Hemodialysis Machine is indicated for acute and chronic dialysis therapy.

I. Technological Characteristics

There are no changes to the technological characteristics of the unmodified The 2008T BlueStar Hemodialysis Machine. The modified The 2008T BlueStar Hemodialysis Machine that is the subject of this submission incorporates software modifications to address user preferences and provide additional user convenience (ease of use).
These modifications do not impact the safety and effectiveness of the device. These software modifications do not expand the capability or change the performance of the 2008T BlueStarTM Hemodialysis Machine (K222952) and its intended use/indications for use. The modified device is equivalent to the un-modified device in terms of water requirements, module options, functional options, performance limits, control parameters, compatible bloodlines, and language options.

The following technical specifications of the modified device remain the same as the unmodified device:

- Safety system
- System performance
- Environmental Requirements
- Transportation and Storage condition
- User Interface (except proposed modifications)
- Hardware and therapy settings
- Accessories Environmental Design
- Alarms
- Accuracy and Controls
- Protection against Mechanical Hazard
- Protection against Electrical Hazard
- Protection against excessive temperature or other hazards
- Manufacturing location and manufacturing processes (assembly, fabrication, testing, shipping, installation and service).

A risk analysis has been completed and potential hazards associated with the modifications are identified and mitigated. Mitigations are verified wherever applicable. All potential risks were deemed acceptable after mitigation. Performance and safety tests were conducted to ensure the safety and effectiveness of the device after the proposed modifications.

J. Performance Data

The performance of the modified device was evaluated according to existing FMCNA procedures, protocols, 'declared performance standards and guidelines of the quality system regulation (21 CFR 820). Design verification and validation tests were conducted to ensure that the modifications described in this submission did not affect the essential performance of the device and the device functions as intended.

The following tests were conducted:

- Software Verification and Validation Testing
- Software Verification (Functional Tests) Regression
- Safety Systems Verification Simulated Dialysis Treatment
- Production Test Procedure
- Unstructured and Static Code Verification

K. Comparison of Modified and Unmodified 2008T BlueStar Hemodialysis Machine

Feature/Aspect	Unmodified Device	Modified Device
Device Name	2008T BlueStarTM Hemodialysis Machine (K222952)	2008T BlueStarTM Hemodialysis Machine (Special 510(k) Submission)
Predicate Device	2008T BlueStarTM Hemodialysis Machine (K222952)	Unchanged
Modifications	No modifications reported	Heparin and Sodium Variation System (SVS) Status, Dialysate Flow Button, Applications Installed - Display, Configurator, Sodium Variation System (SVS) as an Optional Feature, Wireless Adapter (Dual Band)
Indications for Use	Acute and chronic dialysis therapy	Unchanged
Technological Characteristics	No changes to technological characteristics	Software modifications for user preferences and convenience
Performance Data	No reported modifications	Modified device has undergone rigorous testing, including software verification and validation, safety systems verification, simulated dialysis treatment, production test procedure, unstructured and static code verification

Safety and Effectiveness	Equivalent to the unmodified device	Modified device demonstrated to be substantially equivalent, meeting safety and effectiveness standards
Intended Use	Unchanged - acute and chronic dialysis therapy	Unchanged
Wireless Adapter	Not applicable to unmodified device	Dual band (2.5Ghz and 5Ghz) wireless adapter added to support wireless network link for the CDX PC, and supports 802.11a/b/g/n

L. Conclusion

Test results demonstrated that the modified 2008T BlueStar Hemodialysis Machine functions as intended and met pre-determined acceptance criteria. Results of functional validation, summative usability testing and risk analysis indicate that the modified Fresenius 2008T BlueStar Hemodialysis Machine is substantially equivalent to the named predicate device and remains safe and effective for its intended use.