September 18, 2020

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

Re: K201207
Trade/Device Name: CombiSet SMARTECH Hemodialysis Blood Tubing Set with attached Priming Set and Integrated Crit-Line Technology, CombiSet SMARTECH Hemodialysis Blood Tubing Set with attached Priming Set and Integrated Crit-Line Technology, no Heparin Line
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KOC, FJK
Dated: August 18, 2020
Received: August 19, 2020

Dear Denise Oppermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

for Carolyn Y. Neuland, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201207

Device Name
CombiSet SMARTECH Hemodialysis Blood Tubing Set with attached Priming Set and Integrated Crit-Line Technology and CombiSet SMARTECH Hemodialysis Blood Tubing Set with attached Priming Set and Intergrated Crit-Line Technology, no Heparin Line

Indications for Use *(Describe)*
The Blood Tubing Set is a sterile, single use, disposable indicated for use with a prescribed hemodialyzer. The suitability of a particular bloodline/hemodialyzer configuration is the responsibility of the physician.
The Blood Tubing Set is intended for acute and chronic hemodialysis therapy.
The Blood Tubing Set is intended to be used with Fresenius Medical Care 2008® Series K, K2 and T Hemodialysis Machines equipped with Crit-Line hardware.
The Crit-Line Blood Chamber is an optical cuvette designed for use with the Crit-Line monitor's sensor clip during acute and chronic hemodialysis therapy to non-invasively measure hematocrit, percent change in blood volume, and oxygen saturation

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, Senior Director Regulatory Affairs – Devices
Preparation Date:	28 January 2020

5.2. Device Name

Trade Name:	CombiSet SMARTECH Hemodialysis Blood Tubing Sets
Common Name:	Blood Tubing Set
Regulation Name:	Hemodialysis system and accessories
Regulatory Class:	Class II per 21 CFR § 876.5820
Product Code:	KOC/FJK
Product Code Name:	KOC – Accessories, Blood Circuit, Hemodialysis FJK – Set, Tubing, Blood, With and Without Anti-regurgitation Valve
FDA Review Panel:	Gastroenterology/Urology

5.3. Legally Marketed Predicate Device

The legally marketed primary predicate device is the CAREline Hemodialysis Blood Tubing Sets cleared under K172238. The legally marketed secondary predicate device is the Crit-Line Clip (CLiC) Blood Chamber cleared under K152953. These devices have not been subject to a design-related recall.

The Blood Volume Monitor (BVM) Hemodialysis Blood Tubing Set with Attached Priming Set and Transducer Protectors (K120823) is being used as a reference device.

5.4. Device Description

5.4.1. Device Identification:

The CombiSet SMARTECH Hemodialysis Blood Tubing Sets (hereinafter referred to as "CombiSet SMARTECH Bloodlines") are the subject of this 510(k) and are available in two (2) configurations:

- CombiSet SMARTECH Hemodialysis Blood Tubing Set with attached Priming Set and Integrated Crit-Line Technology (hereinafter referred to as the "Standard bloodline")
- CombiSet SMARTECH Hemodialysis Blood Tubing Set with attached Priming Set and Integrated Crit-Line Technology, no Heparin Line (hereinafter referred to as the "No heparin line")

5.4.2. Device Characteristics

The CombiSet SMARTECH Bloodlines are single-use, ethylene oxide (EO) sterilized blood tubing sets.

5.4.3. Environment of Use

The CombiSet SMARTECH Bloodlines are used in environments where acute and chronic hemodialysis are performed.

5.4.4. Brief Written Description of the Device

The CombiSet SMARTECH Bloodlines are part of the extracorporeal hemodialysis circuit. During hemodialysis, the extracorporeal circuit transports arterial blood from the patient's arterial access (e.g., fistula or catheter), through a hemodialyzer, and back to the patient's venous access. When the CombiSet SMARTECH Bloodlines are used with the Crit-Line Sensing System (which includes the Crit-Line Sensor Clip), the proposed devices will provide a clear viewing surface for the Crit-Line Sensor Clip to transmit light through the blood.

5.4.5. Materials of Use

The CombiSet SMARTECH Bloodlines are classified as externally communicating, circulating blood, prolonged contact (> 24 hours to 30 days) duration, Class II (Category B) devices in accordance with FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* (16 June 2016).

The materials used for each component of the CombiSet SMARTECH Bloodlines are listed in Table 1.

Table 1: Materials of Composition

Component	Material
Tubing and Components	Polyvinylchloride (PVC) Polycarbonate (PC)

Table 1: Materials of Composition

Component	Material
	Polypropylene (PP) Polyethylene (PE) Acrylonitrile Butadiene Styrene (ABS) Polyisoprene
Transducer Protector	Polyester Polybutylene Terephthalate (PBT) Polytetrafluoroethylene (PFTE) PC
Integrated Crit-Line Blood Chamber	PVC PE PC
Bonding Solvents	Cyclohexanone 50% Methyl Ethyl Ketone (MEK)/50% Cyclohexanone TetraMEK (95% Tetrahydrofuran/5% MEK)

5.4.6. Key Performance Specifications/Characteristics

The key performance specifications of the CombiSet SMARTECH Bloodlines are outlined in Table 2.

Table 2: Key Performance Specifications

Feature	Specification
Maximum Blood Flow Rate	600 mL/min
Maximum Arterial Pressure	-300 mmHg
Maximum Venous Pressure	+500 mmHg
Pump Segment [Inner/Outer Diameter (ID/OD)]	8.0 mm/12.0 mm
Functional CLiC Chamber Test – Hematocrit (HCT)	The measured HCT using the CombiSet SMARTECH Bloodline has a standard deviation X2 of ≤ 3%, and an average bias of ≤ 1% (of the average HCT) as measured on control blood chambers
Functional CLiC Chamber Test – Oxygen Saturation (O2 Sat)	The measured O2 Sat using the CombiSet SMARTECH Bloodline has a standard deviation X2 of ≤ 3%, and an average bias of ≤ 2% (of the average O2 Sat) as measured on control blood chambers

5.5. Intended Use

The CombiSet SMARTECH Bloodlines are intended for use in acute and chronic hemodialysis therapy.

5.6. Indications for Use

The Blood Tubing Set is a sterile, single use, disposable indicated for use with a prescribed hemodialyzer. The suitability of a particular bloodline/hemodialyzer configuration is the responsibility of the physician.

The Blood Tubing Set is intended for acute and chronic hemodialysis therapy.

The Blood Tubing Set is intended to be used with Fresenius Medical Care 2008® Series K, K^2 and T Hemodialysis Machines equipped with Crit-Line hardware.

The Crit-Line Blood Chamber is an optical cuvette designed for use with the Crit-Line monitor's sensor clip during acute and chronic hemodialysis therapy to non-invasively measure hematocrit, percent change in blood volume, and oxygen saturation.

5.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the CombiSet SMARTECH Bloodlines are substantially equivalent to those of the primary predicate CAREline Bloodlines (K172237) and secondary predicate CLiC Blood Chamber (K152953):

- Indications for Use
- Technological Characteristics
- Design
- Performance Requirements

5.8. Sterilization Testing

The CombiSet SMARTECH Bloodlines are sterilized by exposure to 100% ethylene oxide (EO). The sterility assurance level (SAL) is 10^{-6}. Sterility and non-pyrogenicity are claimed for the fluid pathway of the bloodline.

5.8.1. EO Residual Testing

Residual testing for EO and ethylene chlorohydrin (ECh) was performed in accordance with *AAMI/ANSI/ISO 10993-7:2008/(R)2012 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals*. Acceptable results (i.e., < 4.6 mg/device for EO and ECh) were obtained for the subject bloodlines.

5.8.2. Bacterial Endotoxin (Pyrogenicity) Testing

The subject bloodlines were tested for bacterial endotoxin (pyrogenicity) with Limulus Amebocyte Lysate (LAL) and determined to be non-pyrogenic (< 20 EU/device) in accordance with

ANSI/AAMI/ST72:2011/(R)2016 Bacterial Endotoxins – Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing.

5.8.3. Sterile Barrier Testing

Sterility of the blood pathway is maintained by the sterile fluid path of the device itself which includes the following components:

- Vented Caps
- Transducer Protectors (TPs)
- Tubing and all other components that make up the structural integrity of the bloodline's fluid path

The vented caps were qualified as part of the sterile barrier by microbial challenge tests in accordance with ANSI/AAMI/ISO 11607-1.

The TPs were qualified as part of the sterile barrier by a viral penetration test adapted from ASTM F1671-13.

The tubing and other components were qualified as part of the sterile barrier through the structural integrity test adapted from ISO 8638 and ASTM F2096-11. Testing was performed on samples after aging and distribution simulation.

5.9. Performance Data

Performance testing was conducted in accordance with ISO 8638:2010 and *Guidance for Industry and FDA Staff, Hemodialysis Blood Tubing Sets – Premarket Notification [510(k)] Submissions* (23 April 2008). Testing conducted to support the determination of substantial equivalence is summarized in Table 3.

Table 3: Performance Testing Summary

Test Conducted	Test Objective
Structural Integrity	Demonstrate that the bloodlines can withstand 1.5X the labeled maximum positive and negative pressures
Pump Segment Performance	Evaluate performance characteristics of the bloodlines over the range of the inlet pressures (normally 0 mmHg to -250 mmHg). Flow rate settings will cover up to 600 mL/min.

Table 3: Performance Testing Summary

Test Conducted	Test Objective
Visual Inspection for Endurance and Simulated Use Tests	Endurance Demonstrate that bloodlines perform with no tubing failures (kinking, collapsing, or disconnection) at the maximum labeled flow rate and pressures for not less than 18 hr Simulated Use Demonstrate that bloodlines perform with no tubing failures (kinking, collapsing, or disconnection) under simulated use conditions for not less than 4 hr
Needle Access Port Test	Demonstrate that the needle access ports can withstand 1.5X the labeled pressures after being punctured with the largest gauge needle recommended in the labeling (21 gauge) – 6X for maximum positive pressure, 11X for maximum negative pressure per ISO 8638:2010
DIN Connectors	Demonstrate that the DIN connectors do not leak when subjected to fluid pressure of 300–330 kPa ISO 80369-7:2016 specifies the test method, but it does not specify requirements for hemodialyzer blood compartment port connectors. However, the liquid leakage test from this standard has been adopted using the reference connector from ISO 8638:2010 to test the DIN connectors for this device.
Male and Female Luer Connectors Tests	Demonstrate that the applicable components of the bloodlines meet the dimensional and performance requirements of ISO 80369-7:2016 (Sections 5 and 6)
Visual Inspection for Packaging (Shipping study)	Demonstrate that shipping case, packaging configuration, and palletization pattern maintain the product's structural integrity during manual handling and motorized freight
Tensile Testing	Demonstrate that all bonded engagements in the bloodlines between components, and between components and tubing can withstand a tensile force of 15 lbf
Spike Flow Rate	Demonstrate that the spike, a component of the bloodlines, can deliver not less than 1000 mL of a sodium chloride solution in 10 min under a static head of 1 m
Spike Insertion Force	Demonstrate that the spike, a component of the bloodlines, is capable of piercing and penetrating the closure of an infusion device without coring and with force not exceeding 200 N, when inserted at a rate of 500 mm/min

Table 3: Performance Testing Summary

Test Conducted	Test Objective
Spike Leak Test	Demonstrate that the spike, a component of the bloodlines, will not leak after piercing an infusion device, remaining pierced for 5 hr, and then having an applied internal pressure of 20 kPa for 15 sec
Spike Disconnection Force	Demonstrate that the spike, a component of the bloodlines, is capable of being removed from the insertion point when a removal force is applied at a rate of 100 mm/min. Establish the removal force value.
Labeling Content per FDA Guidance (Blood Tubing Set) and ISO 8638	Verify the Instructions for Use, color coded components, unit labels, shipping carton graphics, and case labels for the bloodlines meet the requirements of ISO 8638:2010 and *Guidance for Industry and FDA Staff: Hemodialysis Blood Tubing Test – Premarket Notification [510(k)] Submissions (April 2008)*
Readability of Barcode with Human Readable Identification Codes	Demonstrate that the barcode information on the outer container labels and unit labels for the bloodlines is capable of being scanned
Level Detector Test	Demonstrate that the venous chamber of the bloodline interfaces correctly with the hemodialysis machine (2008 series) such that the venous clamp will activate (close) when the fluid level inside the venous chamber falls below the sensor heads
Air-Capture Chamber Fill Level	Demonstrate that the recommended fill level of the air-capture chambers is marked
Blood Filter Retention Test	Demonstrate that the blood filter of the bloodlines remains in the assembly position after tests at 1.5X the maximum recommended positive pressure, with a flow rate of 600 mL/min for not less than 18 hr
Transparency of Transducer Protectors	Demonstrate that the machine side of the transducer protectors (TPs) is clear to allow for visual inspection of blood contamination during use
Transducer Protector Leak Test	Demonstrate that the TP is capable of maintaining a secure and leak-free connection to the hemodialysis machine
Viral Retentiveness Test for Transducer Protectors	Demonstrate that the membrane inside the transducer protector prevents can prevent the passage of bacteriophage (Φ X174) from the patient side to the machine side up to a pressure of 600 mmHg for 1 hr
Torque Test (Connection of Blood Chamber to Dialyzer Connector)	Demonstrate that the bond connection between the Arterial DIN connector and the CLiC Blood Chamber can withstand an applied torque of not less than 14.8 in-lbs without creating a leak at 15 psi for 10 min

Table 3: Performance Testing Summary

Test Conducted	Test Objective
Measure Gap between Lenses	Demonstrate that the distance between the lenses from the CLiC Blood Chamber is 0.078 ± 0.005 in
Functional CLiC Chamber Test (Hematocrit)	Demonstrate that the measurement of HCT of the integrated CLiC Blood Chamber has a standard deviation X2 of ≤ 3%, and an average bias of ≤ 1%, when compared to the HCT measurements made using a production blood chamber (CL10041021) as control
Functional CLiC Chamber Test (O2 Sat)	Demonstrate that the measurement of O2 Sat using the IBC blood chamber will have a standard deviation X2 of ≤ 3%, and an average bias of ≤ 2%, when compared to the O2 Sat measurements made using a production blood chamber (CL10041021) as control
Tubing Compliance Test	Demonstrate that tubing is capable of being occlusively clamped by the venous line clamp of the dialysis machine
Clamp Occlusion Test	Demonstrate that tubing is capable of being occlusively clamped by the bloodline clamps

5.9.1. Biocompatibility Testing

Biocompatibility testing was conducted in accordance with ISO 10993-1:2018 and FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (16 June 2016). The following testing was conducted to support the biological safety of the CombiSet SMARTECH Bloodlines:

- Cytotoxicity, Neutral Red Uptake
- Sensitization, Guinea Pig Maximization
- Intracutaneous Irritation
- Material-Mediated Pyrogenicity
- Hemocompatibility, ASTM Hemolysis (Direct and Indirect)
- Hemocompatibility, Dynamic (Mechanical) Hemolysis
- Complement Activation, SC5b-9
- Platelet and Leukocyte Count
- Partial Thromboplastin Time (PTT)
- Semi-quantitative Leachable Chemical Evaluation, 20% Ethanol (Volatiles, Semi-Volatiles, Non-Volatiles, Metals)
- Semi-quantitative Extractable Chemical Evaluation, Water, Hexane, 95% Ethanol (Volatiles, Semi-Volatiles, Non-Volatiles, Metals)

5.9.2. Human Factors Validation Testing

The CombiSet SMARTECH Bloodlines were validated for safe and effective use in accordance with FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices* (03 February 2016).

5.9.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. The CombiSet SMARTECH Bloodlines are not electrical mechanical devices.

5.9.4. Software Verification and Validation Testing

Not applicable. The CombiSet SMARTECH Bloodlines do not contain software.

5.9.5. Animal Studies

No animal studies were performed.

5.9.6. Clinical Studies

No clinical studies were performed.

5.10. Conclusion

The Indications for Use, technological characteristics, design, and performance requirements of the CombiSet SMARTECH Bloodlines are substantially equivalent to those of the predicate devices. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the CombiSet SMARTECH Bloodlines are safe and effective for their intended use.

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.