December 14, 2017

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

Re: K172238
Trade/Device Name: CAREline Airless Hemodialysis Blood Tubing Sets
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: KOC, FJK
Dated: November 10, 2017
Received: November 13, 2017

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,

Charles Viviano -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172238

Device Name
CAREline Airless Hemodialysis Blood Tubing Sets

Indications for Use *(Describe)*

CAREline Twister:
The blood tubing set is 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 Fresenius Access Flow Reversing Connector (AFRC) is for use during hemodialysis to reverse the blood flow to and from the arterial and venous vascular access devices during hemodialysis in order to obtain an access flow measurement. The AFRC facilitates the test procedure by eliminating the need to disconnect bloodlines during the test procedure.
• Blood Tubing Set is intended to be used with the Fresenius Medical Care 2008® Series, K, K2 and T Hemodialysis Machines.

CAREline Standard:
The blood tubing set is indicated for use with a prescribed hemodialyzer. The suitability of a particular bloodline/ hemodialyzer configuration is the resonsiblity of the physician.
• The Blood Tubing Set is intended for acute and chronic hemodialysis therapy.
• Blood Tubing Set is intended to be used with the Fresenius Medical Care 2008® Series, K, K2 and T Hemodialysis Machines.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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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) 699-4479
Fax:	(781) 699-9635
Contact Person:	Denise Oppermann, Senior Director Regulatory Affairs – Devices
Preparation Date:	24 July 2017

5.2. Device Name

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

5.3. Legally Marketed Predicate Device

5.3.1. Primary Predicate - CombiSet® Blood Tubing with Access Flow Reversing Connector (Twister®)

CombiSet Blood Tubing with Access Flow Reversing Connector (Twister), K022536, is the primary predicate for the CAREline Airless Hemodialysis Blood Tubing Sets (hereafter referred to as "CAREline bloodlines").

5.3.2. Secondary Predicate - Streamline Airless System Set with Locksite® Needleless Access Site

Streamline Airless System Set with Locksite Needleless Access Site, K080807, is the secondary predicate for the CAREline bloodlines.

5.4. Device Description

The CAREline bloodlines are intended for use in acute and chronic hemodialysis therapy. The bloodline is part of the hemodialysis extracorporeal circuit, which 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.

5.4.1. Device Identification

The proposed CAREline bloodlines include the following devices (Table 1):

Table 1: Proposed CAREline Bloodlines

Product	Alternate name
CAREline Airless Hemodialysis Blood Tubing Set with Attached Priming Set	CAREline Standard bloodline
CAREline Airless Hemodialysis Blood Tubing Set with Access Flow Reversing Connector (Twister) and Attached Priming Set	CAREline Twister® bloodline

5.4.2. Environment of Use

The CAREline bloodlines are used in environments where acute and chronic hemodialysis are performed.

5.4.3. Brief Written Description of the Device

The CAREline bloodlines are intended for use in acute and chronic hemodialysis therapy. The bloodline is part of the hemodialysis extracorporeal circuit, which 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.

5.4.4. Materials of Use

The CAREline bloodlines are classified as an external communicating medical device with prolonged exposure (>24 hours ≤ 30 days) to circulating blood in accordance with ISO 10993- 1:2009, FDA G95-1, and FDA Guidance on Hemodialysis blood tubing sets (2008).

Materials used in the manufacture of the CAREline bloodlines include:

- Tubing and Components:
  - Polyvinylchloride (PVC)
  - Polycarbonate (PC)
  - Polypropylene (PP)
  - Polyethylene (PE)
  - Methyl Isobutyl Ketone (TetraMEK)

  - Cyclohexanone
- Pressure Output Device (POD):
  - Methyl Methacrylate Acrylonitrile Butadiene Styrene (MABS)
  - Thermoplastic Elastomer (TPE) made of Medalist® MD
- Twister (Twister model only):
  - Acrylic-based polymer (Cryo XT)
  - Polyisoprene Rubber
  - Siloxanes
  - Silicones
  - Dimethyl alcohol
  - Isopropyl alcohol

5.4.5. Key Performance Specifications/Characteristic

The CAREline bloodlines are single-use devices sterilized by ethylene oxide (EO).

The CAREline bloodlines have the following performance characteristics:

- Transmission of arterial and venous pressures to the hemodialysis (HD) machine's pressure transducer via a Pressure Output Device (POD)
- Collection of blood samples and administration of prescribed medications via a needleless access port (T-port)
- Prevention of stretched or kinked tubing via a dialyzer holder lock sleeve (a class I exempt accessory)
- Measurement of a patient's access flow via the Twister component, which is used to reverse blood flow to and from the arterial and venous vascular access sites.

5.5. Intended Use

The CAREline Airless Hemodialysis Blood Tubing Sets are indicated for use in acute and chronic hemodialysis therapy.

5.6. Indications for Use

CAREline Twister

The blood tubing set is 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 Fresenius Access Flow Reversing Connector (AFRC) is for use during

hemodialysis to reverse the blood flow to and from the arterial and venous vascular access devices during hemodialysis in order to obtain an access flow measurement. The AFRC facilitates the test procedure by eliminating the need to disconnect bloodlines during the test procedure.

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

CAREline Standard

The blood tubing set is 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.
- Blood Tubing Set is intended to be used with Fresenius Medical Care 2008® Series K, K^2 and T Hemodialysis Machines.

5.7. Comparison of Technological Characteristics with the Predicate Device

The CAREline bloodlines and the predicate devices share the following characteristics:

- Similar intended use including similar indications for use
- Similar design and configuration
- Same scientific technology and principles of operation
- Same sterilization method, packaging, and sterility label claims
- Same materials – Polyvinylchloride (PVC), Polypropylene (PP), Polyethylene (PE)

5.8. Performance Data

Performance testing was conducted in accordance with ISO 8638:2010. Results of the testing listed below support the determination of substantial equivalence.

- Performance testing of connectors (hemodialyzer, vascular access device, and ancillary components)
- Structural integrity testing
- Biological safety testing (biocompatibility)
- Sterility and pyrogenicity testing
- Structural integrity – Pressure and pull testing
- Pressure testing - Access ports and pressure output devices (PODs)

- Endurance testing – Conducted with Fresenius Medical Care 2008® Series K, K^2, and T Hemodialysis Machines
- Clamp testing – Ability to occlude and effects of repeated use
- Usability evaluation

5.8.1. Biocompatibility Testing

The following testing was performed to support the biological safety of the CAREline bloodlines:

- Chemical analysis – Extractables and leachables
- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Material Mediated Pyrogenicity
- Genotoxicity
- Hemocompatibility

A toxicological risk assessment was also performed.

5.8.2. Electrical Safety and Electromagnetic Compatibility (EMC)

No electrical safety and electromagnetic compatibility (EMC) tests were performed.

5.8.3. Software Verification and Validation Testing

No software verification and validation tests were performed.

5.8.4. Mechanical and Acoustic Testing

No mechanical or acoustic tests were performed.

5.8.5. Animal Studies

No animal studies were performed.

5.8.6. Clinical Studies

No clinical studies were performed.

5.9. Conclusions

Based on the information and data provided in this Traditional 510(k) submission, the CAREline bloodlines are substantially equivalent in intended use, indications for use, design, principle of operation, technology, materials, and performance to the predicate devices (K022536, CombiSet Blood Tubing with Access Flow Reversing connector (Twister) and K080807, Streamline Airless System Set with Locksite Needleless Access Site). The devices are safe and effective for their intended use.