December 13, 2017

Spectral Medical Inc.
% Olga Pavlova, Ph.D.
Regulatory Manager
Amarex Clinical Research
20201 Century Boulevard, 4th Floor
Germantown, MD 20874

Re: K170790
Trade/Device Name: S.A.M CRRT Unit
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: November 10, 2017
Received: November 13, 2017

Dear Olga Pavlova:

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,

Benjamin R. Fisher -S

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)*
K170790/S001

Device Name
S.A.M CRRT Unit

Indications for Use *(Describe)*

The S.A.M CRRT Unit is intended for:

* Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload.

* Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated.

For all treatments performed utilizing the S.A.M CRRT Unit, use of the treatment device must be carried out as per the manufacturers' specifications.

All treatments administered via the S.A.M unit must be prescribed by a physician and are intended to be performed in the environment of the Intensive Care Unit or Emergency Department of the hospital.

Rx Only.

The S.A.M Cassette CRRT is intended for single use in continuous renal replacement and therapeutic plasma exchange therapies using the S.A.M CRRT Unit. The S.A.M Cassette for CRRT is indicated for patients weighing 20 kg or more. Rx Only.

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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SPECTRAL INC Medical

510(k) Summary

The content in this 510(k) summary has been provided in conformance with 21 CFR Part 807.92.

Submitter's Information

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Contact Person: Danijela Domljanovic
Director, Quality Assurance
Date of Preparation: November 20, 2017

Device Name

Trade/Device Name: S.A.M CRRT Unit
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: Class II
Product Code: KDI
Classification Panel: Gastroenterology/Urology

Legally Marketed Predicate Devices (unmodified devices)

Prismaflex™ 510(k) K110823

Device Description

The S.A.M CRRT Unit is a software controlled device that performs the following functions:

- Primes the SAM disposable cassette automatically.
- Pumps blood through the blood flow path of the disposable cassette.
- Delivers anticoagulant into the blood flow path.
- Pumps sterile infusion solutions into the blood flow path of the disposable according to therapy in use.
- Pumps sterile dialysate into the fluid compartment of the filter in CRRT therapies.
- Controls the patient fluid removal or plasma loss according to the therapy in use.

- Monitors the system and alerts the operator to abnormal situations through alarms.

The S.A.M CRRT Unit has a touchscreen interface that provides operating instructions to the user. The system is used in conjunction with the S.A.M Cassette tubing set.

Physical Characteristics:

Height 1600 mm
Width 720 mm
Depth 660 mm
Weight 50kg

Indications for Use

The S.A.M CRRT unit is intended for:

* Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload.

* Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated.

For all treatments performed utilizing the S.A.M CRRT Unit, use of the treatment device must be carried out as per the manufacturers' specifications.

All treatments administered via the S.A.M unit must be prescribed by a physician and are intended to be performed in the environment of the Intensive Care Unit or Emergency Department of the hospital.

Rx Only.

The SAM Cassette CRRT is intended for single use in continuous renal replacement and therapeutic plasma exchange therapies using the SAM CRRT Unit. The SAM Cassette for CRRT is indicated for patients weighing 20 kg or more. Rx Only.

Patient Population:
The intended patient population of the SAM control unit are patients requiring extracorporeal blood purification by convection, diffusion or adsorption including, or not, compensation of the components extracted from the blood. Specifically the unit is intended to deliver the continuous renal replacement therapies (CRRT) continuous veno-venous – Hemofiltration (CVVH or HF), - Hemodialysis (CVVHD or HD), and - Hemodiafiltration (CVVHDF or HDF). The unit will also deliver Therapeutic Plasma Exchange (TPE).

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Technological Characteristics (design, material, chemical composition, energy source, etc.)

Parameter	**Prismaflex** K110823	**SAM**
Intended Use	The Prismnaflex® control unit is intended for: * Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload. * Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated. All treatments administered via the Prismaflex® control unit must be prescribed by a physician	The S.A.M CRRT Unit is intended for: * Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload. * Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated. For all treatments performed utilizing the S.A.M CRRT Unit, use of the treatment device must be carried out as per the manufacturers' specifications. All treatments administered via the S.A.M unit must be prescribed by a physician and are intended to be performed in the environment of the Intensive Care Unit or Emergency Department of the hospital. Rx Only. The S.A.M Cassette CRRT is intended for single use in continuous renal replacement and therapeutic plasma exchange therapies using the S.A.M CRRT Unit. The S.A.M Cassette for CRRT is indicated for patients weighing 20 kg or more. Rx Only.
Technology / Components: Pumps	5 Peristaltic Pumps	4 piston/membrane pumps

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Clamps/Valves	One Venous Electroclamp	8 Cam driven pinch clamps (2 per pump chamber) 3 stepper motor actuated pinch clamps (Venous, purge, waste)
Air / fluid detectors Blood leak detector Pressure transducers	1 Air Detector 1 Optical Blood Leak Detector 4 Pressure Sensors	1 ultrasonic air/ fluid detectors 1 optical blood leak detector 5 electronic pressure transducers
Temperature sensors	No.	4 electronic temperature sensors (one per plate of heater, one for fluid inlet and one for outlet)
Flow Rates: Blood	10-450 ml/min	0-300ml/min
Prescription Fluid /Dialysate Flow	0-8000 ml/h	0-6000 ml/h
Ultrafiltration Flow	0-10000 ml/hr	0-6000ml/hr
Transmembrane Pressure Monitoring Specification	70 to 350mmHg	0-400mmHg
Venous Pressure Monitor	-50 to 350 mmHg	-120 to 300 mmHg
Effluent fluid Pressure Monitor	-350 to 400 mmHg	-50 to 500 mmHg
Air Detector	Yes	Yes
Blood Leak Detector	Yes	Yes
Effluent Volume Accuracy	(+/- 30ml/hr) (+/- 70ml/3hr) (+/- 300ml/24hr)	(+/- 25mL/hr)

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Performance Data

The SAM unit is tested against and conforms to the FDA recognized consensus standards:

- 9-80: IEC 60601-2-16 Edition 4.0 2012-03, Medical Electrical Equipment – Part 2-16: Particular Requirements For The Basic Safety And Essential Performance Of Haemodialysis, Haemodiafiltration And Haemofiltration Equipment.

- 19-4: AAMI ANSI ES60601-1:2005/(R) 2012 and A1:2012 C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD).

- 19-1: IEC 60601-1-2 Edition 3 2007-03 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.

The SAM Cassette bloodlines are tested for biocompatibility as per ISO 10993.

The performance data, specifically the data derived from IEC60601-2-16, indicates that the SAM CRRT Unit is suitable for the intended use of the unit and is therefore substantially equivalent to the predicate device.

Conclusion

The successful testing of the S.A.M CRRT Unit demonstrates safety and effectiveness when used for the defined indications for use and is substantially equivalent to the predicate devices.

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