August 6, 2026

Mozarc Medical US LLC
Carol Ming
Sr. Regulatory Manager
15 New Hampshire
Mansfield, MA 02048

Re: K253469
Trade/Device Name: Ritus™ Safety Fistula Cannula with Anti-Reflux Valve 15G x 30mm (1530VSMM); Ritus™ Safety Fistula Cannula with Anti-Reflux Valve 15G x 38mm (1538VSMM); Ritus™ Safety Fistula Cannula with Anti-Reflux Valve 16G x 30mm (1630VSMM); Ritus™ Safety Fistula Cannula with Anti-Reflux Valve 16G x 38mm (1638VSMM); Ritus™ Safety Fistula Cannula with Anti-Reflux Valve 17G x 30mm (1730VSMM); Ritus™ Safety Fistula Cannula with Anti-Reflux Valve 17G x 38mm (1738VSMM)
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: Class II
Product Code: FIE
Dated: October 10, 2025
Received: October 10, 2025

Dear Carol Ming:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MAURA ROONEY -S

Maura Rooney
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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253469

Device Name

Ritus™ Safety Fistula Cannula with Anti-Reflux Valve

Indications for Use *(Describe)*

Ritus™ Safety Fistula Cannula is intended for use gaining percutaneous vascular access via arteriovenous (AV) fistula for blood removal and blood reinfusion during dialysis, in patients 18 years or older, with kidney failure.

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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510(k) Summary K253469

The 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.

1. Submitter's Information

Name	Mozarc Medical US LLC
Address	15 Hampshire Street Mansfield, MA 02048
Contact Person	Carol Ming (carol.ming@mozarcmedical.com)
Preparation Date	July 31, 2026

2. Device Description

Trade Name	Ritus™ Safety Fistula Cannula with Anti-Reflux Valve
Common Name	Needle, Fistula
Regulation Name	Blood access device and accessories
Regulatory Class	Class II
Product Code	FIE
FDA Review Panel	Gastroenterology and Urology

3. Predicate Device

Predicate Device: JMS SysLoc MINI A.V. Fistula Needle Set (V4) (K142564)

Reference Device: SUPERCATH V (K052267)

4. Device Description

The Ritus™ Safety Fistula Cannulas with Anti-Reflux Valve are composed of a stainless-steel puncture needle and an indwelling polypropylene cannula. They are equipped with an integrated, luer-activated anti-reflux valve to prevent the backflow of blood and a safety cap that covers the needle tip when the puncture needle is removed. The devices come supplied with a V-plug hemostatic valve. The needle-stick prevention feature is intended to minimize accidental needle-stick injuries. The anti-reflux valve feature is intended to minimize blood exposure risk. The V-plug hemostatic valve can also be used to check for blood flashback during insertion. A variety of gauge sizes, lengths, and features are available; product features are detailed on the product packaging.

The product consists of a polypropylene cannula and a hubbed stainless-steel needle in a coaxial configuration. The outer portion of the configuration is the cannula assembly. The cannula is bonded proximally to the cone which is constructed of polypropylene. The cone

component of the cannula portion of the assembly contains an integrated, luer-activated anti-reflux valve that prevents the backflow of blood once vessel access has been attained and the needle assembly is withdrawn. The cannula tip has side holes to help prevent vessel wall occlusion.

The inner portion of the coaxial configuration is comprised of a sharp needle made of stainless steel and a needle hub made of polycarbonate. The needle hub is the portion of the needle assembly that is intended to be gripped as the needle assembly is removed from the cannula. As the needle assembly is removed from the cannula, the polycarbonate safety cap travels along the needle shaft until it locks in place over the sharp needle tip.

Proximal to the needle hub is the v-plug which is constructed of polypropylene. The V-plug is a hemostatic valve that allows air to pass but prevents blood flow. The hemostatic valve allows for blood flashback during insertion. Blood flashback is visible through the transparent needle hub and is used to indicate vascular access.

The Ritus™ Safety Fistula Cannula with Anti-Reflux Valve is offered in three cannula gauge sizes: 15G, 16G, and 17G, and two lengths: 30mm and 38 mm. Each of the gauge sizes is identified by a different colored cone. The 15G is identified by a blue-grey cone; the 16G is identified by a white cone; and the 17G is identified by a red-violet cone.

5. Indications for Use

Ritus™ Safety Fistula Cannula is intended for use gaining percutaneous vascular access via arteriovenous (AV) fistula for blood removal and blood reinfusion during dialysis, in patients 18 years or older, with kidney failure.

6. Comparison to Predicate Device

The technological characteristics, design and performance of the Ritus™ Safety Fistula Cannula with Anti-Reflux Valve is consistent with those of the predicate and reference devices.

- **Intended Use**: The intended use of the proposed and the predicate device is the same.
- **Materials:** Both the proposed and the predicate device have stainless steel puncture needles. The proposed device is comprised of polypropylene V-Plug (not present on predicate) and a polycarbonate/stainless steel safety cap, which is different than the propylene cap on the predicate device. Biocompatibility testing was completed, and the difference in material does not impact the safety or effectiveness of the device.
- **Principles of Operation and Technology**: The proposed device and predicate device have the same fundamental scientific technology.

- **Performance**: The performance of the proposed device and the predicate device are substantially equivalent. Differences in flow rate are due to the differences in material. Performance testing, both bench and clinical testing, demonstrate that the proposed device is as safe and effective as the predicate device.

7. Summary of Technological Characteristics

Overall, the Ritus™ Safety Fistula Cannula with Anti-Reflux Valve is substantially equivalent to the predicate device with respect to intended use, technology, design, and performance. Although there are minor differences in design features with the predicate device, Ritus™ Safety Fistula Cannula with Anti-Reflux Valve is equivalent to the design of the reference device. Materials, biocompatibility, bench, and clinical testing demonstrate that there are no differences that affect safety or effectiveness. Therefore, the proposed device performs as intended and is as safe and effective as the predicate device.

8. Performance Data

Biocompatibility

Biocompatibility testing was conducted based on the requirements of ISO 10993-1:2018 and FDA Guidance on ISO 10993-1. The results of the biocompatibility tests conducted demonstrate that the Ritus™ Safety Fistula Cannula with Anti-Reflux Valve meets the ISO 10993 requirements and is biologically safe for its intended use.

Performance Testing

- **Nonclinical Tests**

  Comprehensive performance testing was conducted on the proposed device to verify compliance with applicable product specifications and relevant standards, including ISO 10555-1:2023, ISO 10555-5:2013, ISO 9626:2016, and ISO 80369-1:2018, and to demonstrate reliable functionality across all critical design features. Testing included evaluation of the luer lock fitting assembly, needle performance, needle-stick prevention mechanisms, anti-reflux valve function, V-plug performance, intravascular catheter integrity, and clinical flow rates. All tests met their predefined acceptance criteria, confirming proper mechanical integrity, leak resistance, safety feature activation, usability, and functional performance across all applicable gauge sizes.

  In addition, comparative performance testing was performed against the predicate device to assess equivalence. Hemolysis and static flow rate testing demonstrated that the proposed device performs similarly to, and does not adversely differ from, the predicate

device. Overall, the results confirm that the proposed device is safe, effective, and performs as intended, with performance that is equivalent to or better than the predicate device.

- **Clinical Tests**

Clinical data supporting the premarket notification were obtained from a prospective, multicenter, single-arm, non-randomized clinical study. The study was performed at three U.S. hemodialysis centers and evaluated the Argyle Safety Fistula Cannula with Anti-reflux Valve during routine clinical use.

A total of 40 subjects were enrolled, of whom 38 subjects underwent at least one cannulation with the study device, contributing 1,148 hemodialysis sessions to the primary analysis set.

Subjects were adult patients (≥18 years) with end-stage renal disease and a mature arteriovenous fistula undergoing in-center hemodialysis, representing the intended use population.

The primary endpoint was the percentage of successful hemodialysis sessions, defined as completion of the prescribed treatment without access-related complications or clinically significant adjustments attributable to the vascular access device.

The clinical study demonstrated a high rate of successful dialysis treatments. Overall, 98.61% (1,132/1,148) of sessions met the predefined success criteria, and the cannulation success rate was approximately 98.9%.

During treatment, adjustments to dialysis prescription parameters, including blood flow rate and treatment duration, were made as part of routine clinical care. Reductions in blood flow rate occurred in 494 of 1,132 (43.6%) successful dialysis sessions, while reductions in treatment duration occurred in 269 of 1,132 (23.8%) successful sessions. The mean reduction in blood flow rate was 23.2 ± 35.7 mL/min, and the mean reduction in treatment duration was 15.3 ± 26.6 minutes. Dialysis sessions were otherwise completed according to routine clinical practice.

Dialysis adequacy was evaluated using available single-pool Kt/V (spKt/V) and urea reduction ratio (URR) measurements. Mean spKt/V was 1.49 ± 0.28, and mean URR was 70.9 ± 6.8%. Because blood urea nitrogen (BUN) samples were not collected for all sessions, some adequacy assessments could not be evaluated. Analysis of the available data, including

sensitivity analyses to address missing values, demonstrated dialysis adequacy comparable to baseline treatments performed using conventional steel needles.

The study demonstrated a favorable safety profile, with a low incidence of device-related complications. Access-related complications occurred in 0.44% (5/1,148) of sessions. Minor infiltrations were reported in 0.26% (3/1,148) of sessions, with no major infiltrations observed. Needle dislodgement occurred in 0.17% (2/1,148) of sessions. No events involving blood loss requiring intervention, hemorrhage, air embolism, infection, arterial puncture, or pseudoaneurysm requiring treatment were reported.

No device-related serious adverse device effects (SADEs) or unanticipated adverse device effects (UADEs) were reported. Adverse events observed during the study were consistent with those expected in an ESRD population and were predominantly unrelated to the study device or procedure. No subjects required procedures to correct access-related complications, and all device-related events resolved without sequelae.

Clinical data collection included protocol deviations related to incomplete laboratory and assessment data, primarily affecting dialysis adequacy measures. Several patients did not have Blood Urea Nitrogen (BUN) measurements drawn appropriately, resulting in missing pre- and post-dialysis BUN values. Consequently, the overall number of evaluable adequacy results, including urea reduction ratio calculations, was reduced.

The clinical results demonstrate that the Argyle Safety Fistula Cannula achieves high rates of successful cannulation and dialysis session completion, exhibits a low rate of access-related complications with no serious device-related adverse events, and maintains dialysis adequacy and blood flow performance comparable to predicate devices.

Based on the totality of the clinical evidence, including safety, effectiveness, adverse event profile, and observed complications, the device demonstrates a safety and performance profile comparable to legally marketed predicate fistula needle devices and supports a determination of substantial equivalence.

- **Conclusion for nonclinical and clinical tests**

The non-clinical and clinical data support the safety of the device and design verification and validation demonstrate that the Ritus™ Safety Fistula Cannula with Anti-Reflux Valve device should perform as intended in the specified use conditions. The clinical data demonstrate that the Ritus™ Safety Fistula Cannula with Anti-Reflux Valve performs comparably to the predicate device that is currently marketed for the same intended use.

9. Summary

The Indications for Use, technological characteristics, design, and performance requirements of the Ritus™ Safety Fistula Cannula with Anti-Reflux Valve are substantially equivalent to those of the predicate and reference devices. Mozarc Medical concludes that within the meaning of the Medical Device Amendments Act of 1976, the Ritus™ Safety Fistula Cannula with Anti-Reflux Valve Hemodialysis System are safe and effective for their intended use.