June 20, 2023

VVT Medical Ltd.
% John Smith
Partner
Hogan Lovells US LLP
555 13th Street, NW
Washington, District of Columbia 20004

Re: K231148
Trade/Device Name: ScleroSafe™ 150 mm, ScleroSafe™ 350 mm
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA, FMF
Dated: April 21, 2023
Received: April 21, 2023

Dear John Smith:

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,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.06.20 13:12:49 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231148

Device Name
ScleroSafe™ 150 mm, ScleroSafe™ 350 mm

Indications for Use *(Describe)*
ScleroSafe Peripheral Venous Aspiration & Infusion Kit with Dual Procedure Syringe (ScleroSafe) is intended for the delivery of Asclera®, an FDA-approved sclerosant (Asclera®), in the treatment of varicosities in superficial veins with a diameter of 2 to 3mm.

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

Submitter: John J. Smith
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Sponsor: Liron Tayeb
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6 Hasadna St.
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Date Prepared: June 15, 2023

Name of Device: ScleroSafe™ 150 mm, ScleroSafe™ 350 mm

Common or Usual Name: Catheter/Syringe

Classification Name: Continuous Flush Catheter/Piston Syringe

Regulatory Class: Class II

Classification Regulation: 21 CFR 870.1210, 21 CFR 880.5860

Product Code: KRA, FMF

Predicate Devices: K201907, ClariVein IC, Merit Medical Systems, Inc.

Reference Devices: K042486, Procedur-10 Syringe Device, Avanca Medical Devices, Inc

Device Description

The subject device, the ScleroSafe™ 150 mm, ScleroSafe™ 350 mm (or ScleroSafe Peripheral Venous Aspiration & Infusion Kit with Dual Procedure Syringe) is intended for the delivery of FDA-approved sclerosant Asclera® in the treatment of varicosities in superficial veins with a diameter of 2 to 3mm.

The ScleroSafe device includes a 5 Fr dual lumen catheter ("DLC"), mountable on a 0.018 inch straight-tipped guidewire in an over-the-wire configuration. The DLC is connected to a hub that splits the catheter into two separate tubes. One of the tubes ends with a blue luer lock for the aspiration extension and the other with a transparent luer lock for the injection extension. Following needle insertion into the vein, the guidewire is removed and a Dual Procedure Syringe ("DPS") is connected to the DLC hub via dedicated luers. The larger syringe (10 ml) is connected to blue luer lock connector (Aspiration Extension) of the catheter and the smaller syringe (5 ml) is connected to a transparent luer lock connector of the catheter (Injection Extension) so fluids are simultaneously injected through one lumen and aspirated through another lumen. ScleroSafe is provided in two sizes: 150mm and 350mm.

As explained in more detail below, ScleroSafe has the same general intended use and similar indications, technological characteristics, and principles of operation as the previously cleared predicate device, the ClariVein IC (K201907) and reference device Procedur-10 (K042486). A substantial equivalence chart comparing the similarities and differences between the ScleroSafe and its predicate device is provided in **Table 1** below.

Intended Use / Indications for Use

ScleroSafe Peripheral Venous Aspiration & Infusion Kit with Dual Procedure Syringe (ScleroSafe) is intended for the delivery of Asclera®, an FDA-approved sclerosant (Asclera®), in the treatment of varicosities in superficial veins with a diameter of 2 to 3mm.

Summary of Technological Characteristics

The ScleroSafe is comprised of a dual lumen catheter, dual procedure syringe, guidewire, needle, and guidewire torque tool. The needle and the guidewire torque tool are off-the-shelf accessories. A comparison of the technical characteristics of the ScleroSafe dual lumen catheter, dual procedure syringe and guidewire to the predicate and reference devices are described below. In addition, substantial equivalence chart comparing the similarities and differences between the ScleroSafe and the predicate (ClariVein IC) and the reference device (Procedur-10) is provided in Table **1** below. Minor differences in the technological characteristics do not raise different questions of safety or effectiveness.

Table 1. Comparison between the Subject, Predicate and Reference Devices

	Subject Device ScleroSafe	**Predicate Device ClariVein IC (Merit Medical)**	**Reference Device Procedur-10 (Avanca)**	**Comments**
Device Name	ScleroSafe	ClariVein IC	Procedur-10 Syringe Device	N/A
510(k) Number	K231148	K201907	K042486	N/A
Intended Use	ScleroSafe is intended for the delivery of Asclera®, an FDA-approved sclerosant (Asclera®), in the treatment of varicosities in superficial veins with a diameter of 2 to 3mm.	The ClariVein IC is indicated for infusion of physician-specified agents in the peripheral vasculature (e.g. superficial veins, saphenous veins).	Avanca's Procedur-10 device is used to inject fluids into, or withdraw fluids from, the body	The subject and predicate devices are both intended for the delivery of agents into the superficial / saphenous veins. In addition, the subject and reference device are both indicated for withdrawal of fluids from the body.
System				
Components	The ScleroSafe is comprised of a dual lumen catheter, Dual Procedure Syringe, needle, guidewire and guidewire torque tool.	The ClariVein IC is comprised of a catheter assembly, including the catheter shaft,	The Procedur-10 device is a piston syringe.	While there are some differences in components the subject device was extensively tested

	Subject Device ScleroSafe	**Predicate Device ClariVein IC (Merit Medical)**	**Reference Device Procedur-10 (Avanca)**	**Comments**
		infusion port, and rotatable wire, and is connected by means of a cartridge to an integral self-contained motor drive unit (MDU). The MDU includes the syringe support, handle grip, wire rotation speed selectors, and trigger features for physician-controlled infusion of a physician-specified agent. The associated accessories includes a 5mL piston style, luer syringe as a convenience for the user.		and found to meet internal specifications, relevant international standards and FDA guidances and no new questions of safety or effectiveness were raised.
Technological Characteristics and mechanism/ principle of operation	Infusion catheter with an inner and outer lumen. When the syringe is depressed the sclerosant is dispersed through holes in the outer lumen at the tip. Simultaneously and automatically blood is withdrawn through the inner lumen which causes the vessel wall to collapse on the catheter. The injection and aspiration are controlled by the handle containing the DPS which is comprised of two syringes that are assembled in a plastic holder. Syringe plungers are connected by a nylon wire and operate with a reciprocal motion.	Infusion catheter with a rotating wire tip designed for the controlled 360-degree dispersion of physician-specified agents to the targeted treatment area. The injection is controlled by the handle containing a syringe and a motor.	Two syringes assembled in a plastic holder. Syringe plungers are connected by a pulley and operate with reciprocal motion. Pressing one plunger enables injection in the syringe while pressing the second plunger enables aspiration in the syringe. Both injection and aspiration are possible, but not simultaneously	While there are minor differences in the mechanism of action, both the subject and predicate devices are infusion catheters that utilize a syringe to disperse a liquid agent into the vein. The subject and reference device both utilize two syringes assembled in a plastic holder that operate in a reciprocal motion to allow for injection and withdrawal of fluid.

	Subject Device ScleroSafe	**Predicate Device ClariVein IC (Merit Medical)**	**Reference Device Procedur-10 (Avanca)**	**Comments**
Sizes	150mm and 350mm	45cm, 65cm, 85cm	N/A	The subject and predicate devices are offered in different sizes however, the size does not raise any new questions of safety or effectiveness.
Compatibility	The device can be used to treat veins ranging in size from 2mm to 3mm in diameter, and can inject between 0-5ml liquid.	The device can be used with 4F introducer sheath, to treat veins from 2mm in diameter, and can inject between 0-5ml liquid.	The device can inject between 0-10ml liquid.	The subject and predicate devices have the capacity to inject the identical quantity of liquid (0-5ml). Both can treat veins in the range of 2-3mm. The capacity for the subject device falls within the capacity of the reference device.
Sterility	The ScleroSafe is labeled sterile (EtO). It has no serviceable or reusable parts. It is entirely disposable post procedure.	The ClariVein IC is labeled sterile (EtO). It has no serviceable or reusable parts. It is entirely disposable post procedure.	The Procedur-10 is labeled sterile (EtO). It has no serviceable or reusable parts. It is entirely disposable post procedure.	Same
Reuse durability	Single use	Single use	Single use	Same
Biocompatibility	Compliant with ISO 10993-1.	Compliant with ISO 10993-1.	Compliant with ISO 10993-1.	Same
Packaging	Tyvek pouch	Pouch	Blister pack	The subject device was tested per the requirements of ISO 11607 and the package integrity was found to be unharmed, functional and effective therefore, no new questions of safety or effectiveness are raised.
Syringe type	Piston syringe	Piston syringe	Piston syringe	Same
Length	14 cm (DPS1005)	Not specified	14 cm	The subject and reference device are the same.
Nozzle type	Male luer lock	Male luer lock	Male luer lock	Same
Volume	5cc 10cc	5 cc	10 cc	Same. The subject device falls within the scope of the predicate device

	Subject Device ScleroSafe	**Predicate Device ClariVein IC (Merit Medical)**	**Reference Device Procedur-10 (Avanca)**	**Comments**
				The subject device has two sizes of syringes, one that is identical to the predicate (5cc) and one that identical to the referenced device (10cc)
Barrel marking specs	Every 1 ml	Every 1 ml	2 ml	The subject and predicate device are the same. The differences between subject and reference devices do not affect volume accuracy therefore, different questions of safety or effectiveness are not raised.
Syringe Housing Material	Polymer (injection molding)	ABS	Polymer (injection molding)	The subject devices were tested per the requirements of ISO 10993 and found to be biocompatible therefore, different questions of safety or effectiveness are not raised.
Guidewire				
Sizes	Diameter - 0.018 inch (0.46mm) Length – 50cm (for ScleroSafe 150mm) 95 cm (for ScleroSafe 350mm)	Diameter - 0.46mm Length – 80 to 150mm	N/A	The subject and predicate guidewires have the same diameter and are offered in multiple lengths. The difference in lengths does not raise any new questions of safety or effectiveness.

Substantial Equivalence Discussion

The ScleroSafe device is substantially equivalent to the predicate device, ClariVein IC (K201907), and reference device, Procedur-10 (K042486). Both devices have the same intended use and similar technological characteristics (*i.e.*, principles of operation, design features, and performance characteristics) as the predicate and reference devices. In particular, the ScleroSafe and ClariVein IC are both infusion catheters that allow the delivery of fluids into superficial veins. In addition, both catheters have a mechanism to ensure that the agent is spread evenly along the wall of the vein. Both

devices are intended for short or transient use, in a health care setting, and are operated by an experienced user.

The key technological differences between the ScleroSafe and its predicate and reference devices include the following:

Differences in principles of operation:

- The main differences between ClariVein IC and ScleroSafe are that ClariVein IC delivers the sclerosant through a rotating wire that touches the vessel wall, while ScleroSafe disperses the sclerosant through holes in the outer lumen and withdraws blood through the inner lumen, causing the vessel wall to collapse on the catheter.
- The Procedur-10 has no catheter.

Differences in handle/syringe:

- The main differences between the ScleroSafe and ClariVein IC regarding the syringe are that (1) the ScleroSafe utilizes a second syringe for the simultaneous withdrawal of blood; and (2) the ClariVein IC utilizes a motor to control rotation whereas the ScleroSafe does not.
- The main difference between the ScleroSafe and Procedur-10 devices is that the ScleroSafe can be also used to simultaneously aspirate and inject fluids while the Procedur-10 device performs aspiration and injection separately.

Performance Data

Design Verification Testing
Design verification testing included testing to demonstrate the functionality and conformance to product requirements of the dual lumen catheter, guidewire and dual procedure syringe. The bench testing was conducted pursuant to FDA Guidance: *Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling* (FDA's 2019 Guidewire Guidance) as well as ISO 10555-1:2013/Amd 1:2017 and ISO 25539-1:2017. All testing demonstrated that the ScleroSafe device met its performance specifications and performed as intended.

Shelf Life
The ScleroSafe is provided in individual sterile packs comprised of a high-density polyethylene (HDPE) tray packaged in a Tyvek® pouch (single sterile barrier). The Tyvek® pouch is placed along with an Instructions for Use, into an individual shelf carton. Multiple shelf cartons are placed in a corrugated shipping box used for storage and transport. Packaging, transportation and shelf-life (both accelerated and real shelf life) studies were conducted according to ISO 11607 and passed all acceptance criteria. All studies were performed on sterile finished product, in compliance with applicable standards. The results demonstrated that the device maintains sterility and functionality throughout its 3 year shelf life.

Biocompatibility
The ScleroSafe device was evaluated for:

a. Complement activation and hemolysis per 10993-4 (Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood);
b. Cytotoxicity per ISO 10993-5 (Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity);
c. Skin irritation and intracutaneous reactivity test per ISO 10993-10 (Biological evaluation of

medical devices – Part 10: Tests for skin irritation and skin sensitization);
d. Acute systemic toxicity and pyrogenicity per ISO 10993-11 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity); and
e. Particulate testing per the requirements of USP <788>.

Biocompatibility testing did not raise any biocompatibility concerns. In addition, particulate testing confirmed that the particulate matter present in the device meets the requirements of USP <788>.

Usability
A human factors engineering usability study was conducted to evaluate device performance of the ScleroSafe for its intended users, uses, and use environments. Both objective and subjective feedback and risk analysis confirm that device performance by the intended users of the ScleroSafe device is acceptable, including performance of critical tasks in the expected use environment.

Animal Testing
A GLP animal study was conducted to evaluate the safety and performance characteristics of the ScleroSafe in an ovine model. The ScleroSafe device demonstrated no clinical adverse events, no extravascular impact, and comparable pathological tissue responses compared to the control device in the chronic sheep saphenous vein sclerotherapy model.

Clinical Testing
The company retrospectively evaluated the subject device in 20 ScleroSafe procedures that were performed in 20 patients in Germany. Twenty subjects (13 female, 7 male) with primary incompetent reticular leg veins (veins 2 to 3 mm in diameter) were treated with the ScleroSafe Procedure kit between January and June 2019. Subjects were included if they met the intended use and were not impacted by the contraindications described in the device's labeling. All subjects were assessed for safety and for obliteration of the vein. Complete obliteration of the vein was achieved in 100% of the patients with no recurrence within 30 days after the treatment (assessed by duplex check at follow up session). Three minor events were reported post procedure (small hematoma and phlebitis); however, they were not considered complications since it was deemed not to be a clinically significant adverse event attributed to the treatment and did not require additional significant treatment.

Conclusions

In conclusion, the ScleroSafe device has the same intended use and very similar technological characteristics to its predicate and reference devices. Any differences in the indications for use and technological characteristics between the subject and predicate device are minor and do not raise new questions of safety or effectiveness. Bench, animal, usability, and clinical testing further support this conclusion and demonstrate that the ScleroSafe is substantially equivalent to the predicate and reference devices for its intended use.