May 2, 2023

TriSalus Life Sciences
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K230957
Trade/Device Name: TriSalus TriNav® LV Infusion System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: Class II
Product Code: KRA, DQO
Dated: April 4, 2023
Received: April 4, 2023

Dear Prithul Bom:

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: 2023.05.02 13:52:07 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230957

Device Name
TriSalus TriNav® LV Infusion System

Indications for Use *(Describe)*
The TriSalus TriNav® LV Infusion System is intended for use in angiographic procedures.
It delivers radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.

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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510(K) SUMMARY

(DATE PREPARED: 01 FEBRUARY 2023

Device Name
TriSalus TriNav® LV Infusion System

Manufacturer Name and Address
TriSalus Life Sciences, Inc.
6272 W. 91st Avenue
Westminster, CO 80031
Owner Operator Number: 10038066

Submitter Contact Information
TriSalus Life Sciences, Inc.
6272 W. 91st Avenue
Westminster, CO 80031
Contact: Michael Aymami, Sr. Director of Regulatory Affairs
Phone: 303-243-4969 Fax: 303-426-1223

Common, Classification & Proprietary Names

Common Name:	Catheter, Continuous Flush
Classification Name:	Catheter, Continuous Flush
Proprietary Name:	TriSalus® TriNav® LV Infusion System
Classification:	Class II
Classification Panel:	Cardiovascular Devices/Coronary and Peripheral Interventional Devices
Classification Regulation:	21 CFR 870.1210
Primary Product Code:	KRA (Primary)
Secondary Product Code:	DQO (Secondary)

Predicate Device
- Surefire Spark Infusion System (rebranded as TriNav) K180677

Reference Device
- Surefire Infusion System K160662

Device Description
The TriSalus® TriNav® LV Infusion System is a 0.025" lumen microcatheter, a self-expanding tip at the distal end. The TriNav® LV serves as the conduit for physician-specified agents such as contrast agents, flush solutions, and embolic beads. It is compatible with standard guide wires with outer diameter up to 0.018" (0.46 mm), guiding catheters with inner diameter at least 0.048" (1.22 mm), embolic hydrogel particles 500 μm or less in size and glass microspheres 110 μm or less in size. The TriNav® LV has a PTFE inner liner to provide a lubricious surface for passage of physician-specified agents and other accessory devices. The device is hydrophilically coated. The soft, pliable, self-expanding tip is sized for use in vessels 3.0 mm to 5.0 mm in diameter. An optional, commercially available hemostasis valve (HV) is included.

There are two radiopaque markers located at the distal end of the TriNav® LV device to aid in positioning of the self-expanding tip. When in correct position, the self-expanding tip is designed to improve infusion efficiency of compatible embolic agents while maintaining antegrade flow in various size vessels.

The TriSalus® TriNav® LV Infusion System is provided sterile (EtO) for single patient use.

The TriSalus® TriNav® LV Infusion System will be available in the following sizes:

Inner Diameter	Length	Tip / Vessel Size
0.025 inch	120 cm	3.0 – 5.0 mm
0.025 inch	150 cm	3.0 – 5.0 mm

Indications for Use

The TriSalus TriNav® LV Infusion System is intended for use in angiographic procedures.
It delivers radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.

Substantial Equivalence

The TriSalus® TriNav® LV Infusion System is substantially equivalent in intended use, design, and technology/principles of operation to the predicate device. Where the proposed device has been scaled to accommodate the larger vessel sizes for which it is recommended the proposed device sizing is equivalent to the reference device.

Comparative Summary: Design / Technological Characteristics

The TriSalus® TriNav® LV Infusion System is similar in design to the predicate device. Both devices are microcatheters with an expandable tip on the distal end. Both the proposed TriSalus® TriNav® LV Infusion System and the predicate Surefire Spark Infusion system (rebranded as TriNav) leverage a single-lumen microcatheter design. Both devices employ a self-expanding tip. Both the proposed and predicate devices use an introducer to collapse the tip so that it can be introduced into the guide catheter.

The TriSalus® TriNav® LV Infusion System and the predicate device are constructed of similar materials utilizing similar construction and manufacturing processes.

The TriSalus® TriNav® LV Infusion System and the predicate device have equivalent lengths while the proposed device has a larger diameter to accommodate selective therapy delivery to larger vessel sizes.

The TriSalus® TriNav® LV Infusion System and the predicate device are provided in identical packaging, sterilized by ethylene oxide, and labeled for single use only.

Comparative Summary: Indications for Use

The TriSalus® TriNav® LV Infusion System has the same indications for use as the predicate device. Both devices are intended for use in angiographic procedures to deliver radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.

Comparative Summary: Performance

Animal and bench performance test data demonstrate that The TriSalus® TriNav® LV Infusion System performance is comparable to the predicate device.

Biocompatibility Testing

Biocompatibility testing of the patient-contact materials used in the construction of the catheter was performed in accordance with ISO 10993-1 for an external communicating device in contact with circulating blood with a limited duration of less than 24 hours. The following testing was conducted in accordance with GLP by NAMSA (Northwood, OH).

Category	Standard	Test Method
Cytotoxicity	ISO 10993-5	Cytotoxicity Study Using the ISO Elution Method – 1x Minimal Essential Media Extract
Sensitization	ISO 10993-10	ISO Maximization Sensitization Study – Extract – 0.9% Sodium Chloride Solution Extract
		ISO Maximization Sensitization Study – Extract – Sesame Oil, NF Extract
Irritation or Intracutaneous Reactivity	ISO 10993-10	ISO Intracutaneous Study – Extract – 0.9% Sodium Chloride Solution Extract
		ISO Intracutaneous Study – Extract – Sesame Oil, NF Extract
Systemic Toxicity	ISO 10993-11	ISO Systemic Toxicity Study – Extract – 0.9% Sodium Chloride Solution Extract
		ISO Systemic Toxicity Study – Extract – Sesame Oil, NF Extract
		Pyrogen – Material Mediated – 0.9% Sodium Chloride Solution Extract
Hemocompatibility	ISO 10993-4	ASTM Hemolysis – CMF-PBS Extract
		C3a Complement Assay – Normal Human Serum Extract
		SC5b-9 Complement Assay – Normal Human Serum Extract
		Coagulation – ASTM Partial Thromboplastin Time

Additionally, testing for thrombogenicity was performed on the TriSalus® TriNav® LV Infusion System as a part of an Animal Study.

The results of the biocompatibility testing did not indicate any significant biological reaction that would affect the patient due to contact with the materials used in the device construction.

Performance Testing

The following design verification / validation tests were performed. The test results demonstrate that the TriSalus® TriNav® LV Infusion System meets the same performance specifications and acceptance criteria as the predicate device.

- Visual and Dimensional
- Tensile (Pull) Strengths
- Kink Radius
- Torque Resistance
- Burst Pressure
- Hub Aspiration
- Hub Solvent Compatibility
- Coating Durability and Uniformity
- EtO Residuals
- Coating Frictional Force
- Base Catheter Insertion/Retraction Force
- Diagnostic Agent Compatibility
- Embolic Agent Compatibility
- Infusion Efficiency
- Antegrade Flow
- Particulates
- Pouch Integrity
- Pouch Seal Strength

Animal Testing

An animal study was performed to assess the comparative acute performance of the TriSalus® TriNav® LV Infusion System to the predicate device, as defined by physicians in a simulated clinical environment. The TriSalus® TriNav® LV Infusion System was found to be acceptable in all evaluated categories, met the defined user needs, and performed comparably to the predicate device.

Clinical Testing

No clinical testing was required to demonstrate the substantial equivalence of the subject device to its predicates. Therefore, no pre-market clinical testing was performed nor is any included within this 510(k) submission.

Conclusion

In summary, The TriSalus® TriNav® LV Infusion System is substantially equivalent in intended use, design, and technology/principles of operation to the predicate device. Animal and bench performance test data demonstrate The TriSalus® TriNav® LV Infusion System has substantially equivalent safety, effectiveness, and performance outcomes as the predicate device. Differences between the devices do not raise different questions of safety or effectiveness.