December 27, 2023

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

Re: K233858
Trade/Device Name: TriSalus TriGuide™ Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 5, 2023
Received: December 5, 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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Samuel G. Raben -S

for Lydia Glaw
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)*
K233858

Device Name
TriSalus TriGuide Guiding Catheter

Indications for Use *(Describe)*
The TriSalus TriGuide Guiding Catheter is designed to provide a pathway through which therapeutic devices are introduced. The TriSalus TriGuide is intended to be used 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) #: K233858

510(k) Summary

Prepared on: 2023-11-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	TriSalus Life Sciences
Applicant Address	6272 W. 91st Ave Westminster Co 80 United States
Applicant Contact Telephone	3032434969
Applicant Contact	Mr. Michael Aymami
Applicant Contact Email	michael.aymami@trisaluslifesci.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TriSalus TriGuideTM Guiding Catheter (TGC-48065-Axis TGC-48065-Sim1 TGC-48065-Cobra)
Common Name	Percutaneous catheter
Classification Name	Percutaneous Catheter
Regulation Number	870.1250
Product Code	DQY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K140034	Surefire Guiding Catheter	DQY

Device Description Summary

21 CFR 807.92(a)(4)

The TriSalus TriGuideTM Guiding Catheter provides a pathway to introduce and facilitate the advancement of devices into the peripheral vascular system. Its principle of operation is therefore to provide a patent pathway for compatible accessories as described within its labeling.

TriSalus TriGuideTM Guiding Catheter is a single-lumen, braided, fixed-length 5F catheter with a soft distal tip and a proximal Luer-Lock hub and strain relief. The TriSalus TriGuideTM Guiding Catheter has a three-layer construction, consisting of a PTFE inner liner, stainless steel braid mid-layer, and an extruded Pebax polymer outer shaft jacket. The Pebax extruded polymer is filled with barium sulfate ($BaSO_4$) as a
radiopacifier, to provide visibility of the TriSalus TriGuideTM Guiding Catheter under fluoroscopy.

The TriSalus TriGuideTM Guiding Catheter are 65 cm in length in three pre-shaped tip designs including Axis, Sim 1, and Cobra to accommodate access and positioning in
a range of peripheral vascular anatomies. The distal tip is rounded for atraumatic vessel tracking.

Product Code	Tip	Overall Length	Usable Length	Tip Length	ID	OD
TGC-48065-AXIS	Axis	75cm	67cm	4cm	0.048"	5F
TGC-48065-SIM1	Sim1	75cm	67cm	6cm	0.048"	5F
TGC-48065-COBRA	Cobra	75cm	67cm	7cm	0.048"	5F

The TriSalus TriGuideTM Guiding Catheter is compatible with standard 0.038" OD guide wires, Luer-Lock infusion syringes, rotating hemostatic valves (RHV), and 5F catheter sheath introducers.

The TriSalus TriGuideTM Guiding Catheter is provided sterile (EtO) for single-patient use. The device utilizes no lubricious coatings.

Device Materials (All device shape variants)

Outer Jackets (Direct Contact) = Pebax 4033 SA01 MED, Pebax 5533 SA01 MED, Pebax 6333 SA01 MED, Pebax 7233 SA01 MED
Braid (Indirect Contact) = 304 Stainless Steel
Braid Cover (Indirect Contact) = Polyethylene terephthalate (PET)
Liner (Direct Contact) = PTFE, Bismuth Trioxide, Black 26, Titanium Dioxide, <.1% Proprietary
Radiopacifiers (Direct Contact) = Barium Sulfate
Colorants (Direct Contact) = Jacket - Black Colorant (Monarch Black-C), Jacket - Blue Colorant (Clariant 2945C), Strain Relief - White Colorant (Titanium Dioxide), Hub - White Colorant (Mevopur AI0M176004)
Strain Relief(Indirect Contact) = Pebax 5533 SA01 MED, Pebax 6333 SA01 MED
Hub (Indirect Contact) = Grilamid TR55LX

Device Contract type/duration: Contact with circulating blood with a limited duration of fewer than 24 hours (<24 hrs.)

Packaging Materials (All device shape variants)

Backer Card = HDPE
Label (Pouch and Carton) = Transtherm 1C, S246 Adhesive, 40# Liner
Pouch = CT coated Tyvek 1073B
Instructions for Use = #50
Carton = .024" SBS
Shipper = 275LB Corrugated B/C Flute
Closure Label = Transtherm 1C, S246 Adhesive, 40# Liner

All three device shape variants are packaged in the same manner. One device is loaded onto a backer card. The carded device is loaded into a prelabeled pouch which is then sealed. The pouched device is loaded into a carton with the IFU placed on the non-breathable portion of the pouch and the carton is labeled and sealed. Each carton contains one TriGuide device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The TriSalus TriGuideTM Guiding Catheter is designed to provide a pathway through which therapeutic devices are introduced. The TriSalus TriGuideTM is intended to be used in the peripheral vascular system.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications of use for the proposed device are identical to the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

SUBSTANTIAL EQUIVALENCE
Predicate Device

The TriSalus TriGuideTM Guiding Catheter is substantially equivalent in indications for use, intended use, design, principles of operations, mechanical performance, and technological characteristics to the cleared predicate device.

Primary Predicate Device Name 510(k)
 Surefire Guiding Catheter K140034

Substantial Equivalence Comparison
A Substantial Equivalence Matrix comparing the features of the TriSalus TriGuideTM Guiding Catheter with the predicate device is provided.

Classification
The TriSalus TriGuideTM Guiding Catheter is a Class II medical device identical to the the predicate.

Indications for Use

The TriSalus TriGuideTM Guiding Catheter has identical indications for use and contraindications as the predicate Surefire Guiding Catheter. Both devices are designed to provide a pathway through which therapeutic devices are introduced. The TriSalus TriGuideTM Guiding Catheter is intended to be used in the peripheral vascular system.

Design
The TriSalus TriGuideTM Guiding Catheter is equivalent in design to the predicate device. Both devices are guiding catheters with atraumatic tips on the distal end.
Like the predicate device, the TriSalus TriGuideTM Guiding Catheter employs a single lumen microcatheter design.
The TriSalus TriGuideTM Guiding Catheter device preparation is equivalent to its predicate and requires no new or additional steps and is consistent with established standard catheter preparation techniques.

Dimensions
The TriSalus TriGuideTM Guiding Catheter has similar dimensions to the predicate device. Both devices are offered in 65 cm lengths across the three industry-standard tip shape variants of Axis, Sim 1, and Cobra. The inner diameters and outer diameters of both the TriSalus TriGuideTM Guiding Catheter and its predicate are functional equivalent.

Materials
The TriSalus TriGuideTM Guiding Catheter is constructed of materials similar to the predicate device. All materials are commonly used in the manufacture of commercially available intravascular catheters.
Both catheters have a PTFE inner liner, stainless steel reinforcing braid, and a Pebax outer jacket impregnated with equivalent colorants and barium sulfate as a radiopacifier.
The TriSalus TriGuideTM Guiding Catheter employs the same hub material as the predicate device.

Packaging, Labeling, Sterilization
The TriSalus TriGuideTM Guiding Catheter and the predicate device are provided in identical packaging, sterilized by ethylene oxide, have the same EO residual limits and are labeled as single use only.

Performance
The TriSalus TriGuideTM Guiding Catheter has equivalent performance to the predicate device.
As demonstrated in the design verification testing, the TriSalus TriGuideTM Guiding Catheter has been demonstrated to have equivalent to the predicate device with respect pull strengths, kink resistance, torque resistance, burst pressure, hub aspiration, shape retention, pouch integrity, and pouch seal strength.

Simulated clinical use testing conducted in a porcine model further demonstrated that the TriSalus TriGuideTM Guiding Catheter has equivalent performance to the predicate device.

Conclusion
The TriSalus TriGuideTM Guiding Catheter is substantially equivalent to the predicate in intended use, design, technology, and principles of operation. Both animal and bench performance test data demonstrate that the TriSalus TriGuideTM Guiding Catheter performance is equivalent to the predicate device and that any differences between the two devices do not raise any issues of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance testing approach for the subject device was equivalent to the predicate, inclusive of both design verification (bench testing) and design validation (animal testing). Discrete test methods are further enumerated withing the aforementioned test protocols and their resultant reports.

All design verification acceptance criteria and test methods are identical to the predicate with the exception of "High Pressure Injection & Leak" test method which was enhanced as described below:

High Pressure Injection & Leak

Predicate: 600psi static burst

Proposed: 600psi dynamic verification followed by 300kpa static burst for leak test

Incorporated power injection verification step prior to burst test

Justification/Rationale: Updated testing approach to better differentiate between static and dynamic requirements

Not Applicable

The enclosed test results demonstrate that the TriSalus TriGuideTM Guiding Catheter meets the specified acceptance criteria and is substantially equivalent to its predicate without raising new questions regarding safety or efficacy.