



September 21, 2026

Trisalus Life Sciences
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K253509

Trade/Device Name: TriSalus TriNav Advance Infusion System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: June 12, 2026
Received: June 15, 2026

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 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,

LYDIA S.
GLAW -S

Digitally signed by
LYDIA S. GLAW -S
Date: 2026.09.21
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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

Indications for Use

510(k) Number (if known)

K253509

Device Name

TriSalus TriNav Advance Infusion System

Indications for Use (Describe)

The TriSalus TriNav Advance 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.

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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	TriSalus Life Sciences
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Applicant Contact Telephone	303 243 4969
Applicant Contact	Mr. Michael Aymami
Applicant Contact Email	michael.aymami@trisaluslifesci.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	TriSalus TriNav Advance Infusion System ADV-38150-50 ADV-38150-35 ADV-38130-50 ADV-38130-35 ADV-38115-50 ADV-38115-35 ADV-38095-50 ADV-38095-35
Common Name	Continuous flush catheter
Classification Name	Catheter, Continuous Flush
Regulation Number	870.1210
Product Code(s)	KRA, DQO

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K230957	TriSalus TriNav LV Infusion System	KRA

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The TriSalus TriNav Advance Infusion System is a 0.0385" lumen microcatheter with a self-expanding tip at the distal end. Its principle of operation is to serve as the conduit for physician-specified agents such as contrast agents, flush solutions, and embolic beads. The TriSalus TriNav Advance Infusion System is compatible with standard guide wires with outer diameter up to 0.038" (0.97 mm), guiding catheters with an inner diameter at least 0.056" (1.42 mm), embolic hydrogel particles 1300 µm or less in size and glass microspheres 110 µm or less in size. The TriSalus TriNav Advance Infusion System has a Teflon 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 1.8-3.5mm or 3.5-5.0mm, depending on the corresponding valve size. There are two radiopaque markers located at the distal end of the TriNav Advance 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 device is solvent compatible.

The TriSalus TriNav Advance Infusion System is packaged in a primary Tyvek/Mylar pouch that acts as a sterile barrier when sealed. An optional, commercially available hemostasis valve (HV) is included for convenience, along with a second peelable introducer. The hemostasis valve accessory is identical to that which is provided with the predicate TriSalus TriNav LV (K230957). This identical

hemostasis valve is commercially distributed as Merit Flo50. Its FDA Product Code is DTL and it is a Class II, 510(k) exempt medical device per 21 CFR 870.4290. The hemostasis valve accessory is contained within its own Tyvek/Biax Nylon pouch, as received from its manufacturer Merit Medical, and is included within the primary Tyvek/Mylar sterile barrier pouch along with the TriSalus TriNav Advance Infusion System.

The system is provided sterile (EO) for single patient use.

The TriSalus TriNav Advance Infusion System is offered in 95cm, 115cm, 130cm, and 150cm usable length variants with two self-expanding tip sizes of 3.5mm and 5.0mm maximum outer diameter. The model numbers of all device variants are provided below, along with their corresponding recommended vessel sizes.

Model Number	Device Variant	Recommended Vessel Size
ADV-38150-50	150cm usable length, 5.0mm tip	3.5-5.0mm
ADV-38150-35	150cm usable length, 3.5mm tip	1.8-3.5mm
ADV-38130-50	130cm usable length, 5.0mm tip	3.5-5.0mm
ADV-38130-35	130cm usable length, 3.5mm tip	1.8-3.5mm
ADV-38115-50	115cm usable length, 5.0mm tip	3.5-5.0mm
ADV-38115-35	115cm usable length, 3.5mm tip	1.8-3.5mm
ADV-38095-50	95cm usable length, 5.0mm tip	3.5-5.0mm
ADV-38095-35	95cm usable length, 3.5mm tip	1.8-3.5mm

All device variants are packaged in the same manner. Each device is loaded into a packaging hoop. The hooped device and pouched hemostasis valve are loaded into a prelabeled pouch which is then sealed. The pouched device is loaded into a carton, whereafter the carton is labeled and sealed. Each carton contains one TriSalus TriNav Advance Infusion System device.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The TriSalus TriNav Advance Infusion System is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites 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 Comparison

A Substantial Equivalence Matrix comparing the features and performance of the TriSalus TriNav Advance Infusion System to the predicate TriSalus TriNav LV Infusion System device is provided with this submission. The differences between the subject device and the predicate device are in dimensions and materials.

Classification

The TriSalus TriNav Advance Infusion System is a Class II medical device identical to the predicate TriSalus TriNav LV Infusion System device. Both devices are regulated as Continuous Flush Catheters under 21 CFR 870.1210. Both devices carry a primary product code of KRA (Continuous flush catheter) along with a secondary product code of DQO (Diagnostic intravascular catheter) under the remit of the Cardiovascular Review Panel.

Indications / Contraindications

The TriSalus TriNav Advance Infusion System has identical indications for use and contraindications as the predicate device. Both devices are intended for use in angiographic procedures, delivering radiopaque media and therapeutic agents to selected sites in the peripheral vascular system. Both devices are not intended for use in the vasculature of the central nervous system (including the neurovasculature) or central circulatory system (including the coronary vasculature).

Design

The TriSalus TriNav Advance Infusion System is equivalent in design to the predicate device. Both devices are continuous flush, single-lumen microcatheters with self-expanding tips at the distal end employing identical principles of operation. Like the predicate device, the TriSalus TriNav Advance Infusion System employs a single-lumen microcatheter design. Preparation of the TriSalus TriNav Advance Infusion System is identical to the predicate device and requires no new or additional steps, and is consistent with established standard microcatheter preparation techniques. Usage of the TriNav Advance Infusion System is also identical to the predicate device and is consistent with established standard microcatheter utilization techniques.

Dimensions

The TriSalus TriNav Advance Infusion System has similar dimensions to the predicate device. Both devices are offered in usable length variants up to 150cm. The subject device is offered in usable lengths of 95, 115, 130, and 150 cm while the predicate in 120 and 150 cm. Both devices are offered with expandable tip outer diameter variants up to 5.0 mm i.e., 3.5 and 5.0 mm for the subject device and 5.5 mm for the predicate. Both devices are recommended for use in vessels up to 5.0mm for the 5.0 mm tip size and the subject device has an additional 3.5 mm tip size recommended for use in 1.8-3.5 mm vessel. The inner diameters, outer diameters, and hub design of both the TriSalus TriNav Advance Infusion System and its predicate are functionally equivalent.

Materials

The TriSalus TriNav Advance Infusion System is constructed of materials identical or equivalent 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 different colorants and employ self-expanding tips at the distal end.

The TriSalus TriNav Advance Infusion System employs the same type of hub material as the predicate device.

Packaging, Labeling, Sterilization

The TriSalus TriNav Advance Infusion System and the predicate device are provided in identical packaging, sterilized by ethylene oxide, have the same EO residual limits, and are both labeled as single-use only.

Performance

The TriSalus TriNav Advance Infusion System has equivalent performance to the predicate device.

As demonstrated in the provided design verification testing, the TriSalus TriNav Advance Infusion System has been demonstrated to have equivalent performance to the predicate device with respect to pull strength, kink resistance, torque resistance, burst pressure, hub aspiration, particulate shedding, infusion efficiency, insertion/retraction force, vertical pinch friction test, and infusion efficiency. The vessel diameter selected for the antegrade flow model leveraged in design verification testing was scaled appropriately for the recommended vessel sizing of the proposed devices variants. The acceptance criteria of the antegrade flow testing did not change and remains identical to the predicate ensuring that no questions about safety and effectiveness are raised. The TriNav Advance Infusion System is solvent compatible.

Simulated clinical use testing conducted in a porcine model further demonstrated that the TriSalus TriNav Advance Infusion System has equivalent performance to the predicate device.

Conclusion

In summary, the TriSalus TriNav Advance Infusion System 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 TriNav Advance Infusion System 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\(b\)](#)

The performance testing approach for the TriNav Advance Infusion System was equivalent to the predicate device, inclusive of both design verification (bench testing) and design validation (animal testing). Discrete test methods are further enumerated within the aforementioned test protocols, and their resultant test reports are included with this submission.

Design verification and validation testing were completed successfully, demonstrating the equivalence of the TriNav Advance Infusion System in comparison to the predicate device. No new concerns of safety or effectiveness were raised as a result of performance testing.

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