September 22, 2025

AngioSafe, Inc.
Rebecca Spelich
Associate Director, Global Regulatory Affairs
5215 Hellyer Avenue
Suite 240
San Jose, California 95138

Re: K252315
Trade/Device Name: Santreva™-ATK Endovascular Revascularizton Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: July 24, 2025
Received: July 25, 2025

Dear Rebecca Spelich:

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.

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,

GREGORY W. O'CONNELL -S

Digitally signed by GREGORY W. O'CONNELL -S
Date: 2025.09.22 14:04:54 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
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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)*
K252315

Device Name
Santreva™-ATK Endovascular Revascularization Catheter

Indications for Use *(Describe)*
The Santreva™-ATK Endovascular Revascularization Catheter is intended to facilitate the intraluminal placement of guidewires beyond stenotic lesions, including Chronic Total Occlusions (CTOs), in the femoropopliteal (arterial) peripheral vasculature.

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

510(k) Notification K252315

1. Submitter Information

Submitter:	AngioSafe, Inc. 5215 Hellyer Avenue, Suite 240 San Jose, CA 95138 USA
Phone:	(719) 482-4852
Contact Person:	Rebecca Spelich, MSCR
Date Prepared:	September 22, 2025

2. Subject Device

Device Name:	Santreva™-ATK Endovascular Revascularization Catheter
Common Name:	Catheter for Crossing Total Occlusions
Classification Name:	Percutaneous catheter (21 CFR 870.1250)
Regulatory Class:	II
Product Code:	PDU

3. Predicate Device

Predicate Device Name: FRONTRUNNER CTO Catheter, K033535

4. Device Description

Santreva™-ATK Endovascular Revascularization Catheter ("Santreva-ATK") consists of:

1) a distal end mechanism of simultaneous plaque-puncturing, lateral plaque displacement, and plaque compression by a distal tip to form a channel,
2) an intraluminal control mechanism for intraplaque traversal of the distal tip,
3) an outer catheter shaft,
4) an inner torque cable tube with guidewire lumen, and
5) a proximal end handle with integrated torque wheel for manual rotation of the torque cable.

The handle has a luer for introduction of a guidewire through the handle and the torque cable for placement into distal true lumen after Santreva-ATK traverses and recanalizes the plaque without a wire.

The distal catheter has a rotating tip with an integrated cutting loop to puncture, displace, and compress the plaque as the mechanism of CTO crossing in combination with a centering system component to maintain the catheter in the intraluminal and intraplaque position. The centering system component has three collapsible wings and in combination with the distal tip advances into the open lumen of the vasculature and within the CTO which may facilitate formation of an intraplaque and angiographically visible channel. The collapsible centering system wings are sloped in each direction to present a tapered interface to both the CTO body plaque and to the support accessories such as guide catheters or guiding sheaths during advancement and retraction of the catheter.

After delivery of the Santreva-ATK distal catheter tip to the CTO lesion, the operator pushes the outer catheter shaft in the distal direction with one hand, while rotating the handle wheel with the other hand,such that the tip and cutting loop combination punctures the CTO cap. Continued push and rotation of the tip and cutting loop combination recanalizes the CTO plaque with simultaneous radial displacement and compression. As the operator advances the device through the CTO body, the plaque is further compressed laterally by the centering system wings, thereby crossing and recanalizing the CTO intraluminally in a controlled manner. Once the distal tip reaches and punctures the distal cap, the guidewire positioned inside

the inner torque cable lumen is advanced into the distal true lumen, and the device is pulled out through the channel it formed, and through the accessories outside the body. The immediate result is a lumen gain and blood flow restoration through a channel formed by Santreva-ATK, revascularizing the previously ischemic distal zone, and allowing for a guidewire to be placed through this channel into the distal true lumen for further imaging and treatment.

Santreva-ATK has a working length of 135 cm and maximum crossing profile of 7.2 Fr (2.4 mm) with the centering system expanded.

Santreva-ATK is compatible with 6 Fr (of 0.070 inch Minimum ID) or larger guide catheters.

Santreva-ATK is also compatible with 5 Fr (of 0.070 inch Minimum ID) or larger guiding sheaths when not using a guide catheter.

5. Indications for Use

The Santreva™-ATK Endovascular Revascularization Catheter is intended to facilitate the intraluminal placement of guidewires beyond stenotic lesions, including Chronic Total Occlusions (CTOs), in the femoropopliteal (arterial) peripheral vasculature.

6. Comparison of Technological Characteristics

Comparison Table: Santreva-ATK Catheter and FRONTRUNNER CTO Catheter

	Santreva™-ATK Endovascular Revascularization Catheter (Subject Device), K252315	**FRONTRUNNER CTO Catheter (Predicate), K033535**
Regulatory Information		
Product Code(s)	PDU	PDU; DQY
Device Classification	II	II
21 CFR Classification	820.1250	820.1250
Regulation Description	Percutaneous catheter	Percutaneous catheter
Target Population	Adult patients with peripheral arterial disease (PAD)	Adult patients with peripheral arterial disease (PAD)
Prescription / Over-the-Counter Use	Prescription Use	Prescription Use
Device Use		
Indications for Use	The Santreva™-ATK Endovascular Revascularization Catheter is intended to facilitate the intraluminal placement of guidewires beyond stenotic lesions, including Chronic Total Occlusions (CTOs), in the femoropopliteal (arterial) peripheral vasculature.	The FRONTRUNNER CTO Catheter is intended to facilitate the intraluminal placement of conventional guide wires beyond stenotic lesions (including chronic total occlusions) in the peripheral and coronary vasculature prior to further percutaneous intervention.
Intended Use	The Santreva™-ATK Endovascular Revascularization Catheter is intended to facilitate the intraluminal placement of guidewires beyond stenotic lesions, including Chronic Total Occlusions (CTOs) in the femoropopliteal (arterial) peripheral vasculature.	The FRONTRUNNER CTO Catheter is intended to facilitate the intraluminal placement of conventional guide wires beyond the stenotic lesions (including chronic total occlusions) in the peripheral and coronary vasculature prior to further percutaneous intervention.
Single Use	Single Use Only	Single Use Only
Anatomic Application Site	Peripheral Vasculature: Femoropopliteal Arteries	Peripheral Vasculature, Coronary Vasculature

Use Environment	Professional healthcare facilities (e.g., catheterization laboratories and vascular surgery suites)	Professional healthcare facilities (e.g., catheterization laboratories and vascular surgery suites)
Users	Trained and qualified healthcare professionals	Trained and qualified healthcare professionals
Design Specifications and Technological Characteristics		
Outer Diameter	Distal Tip: 1.35 mm (4.1 Fr) Centering System: 2.4 mm (7.2 Fr) Distal Catheter Shaft (95 cm): 1.12 mm (3.4 Fr) Proximal Catheter Shaft (40 cm): 1.6 mm (4.8 Fr)	Distal Actuating Tip: 1.00 mm (3.0 Fr) Distal Jaw (open): 2.3 mm (6.9 Fr) Catheter Shaft: 1.03 mm (3.1 Fr)
Working Length	135 cm	140 cm (FBP39140 model) 90 cm (FBS3990 model)
Principles of Operation / Mechanism of Action	A large profile atraumatic tip with a forward-facing cutting loop mounted on a plaque compression tip, controlled by a torque wheel at the handle end, and a larger profile centering wing system at the disease end. The manual torque wheel on the catheter handle controls the cutting loop/tip ensemble rotation, enabling the catheter to cross the CTO by puncturing, displacing, and compressing the CTO plaque simultaneously. In addition, the device may form an angiographically visible channel, with the combined cutting loop/tip ensemble and centering system.	A low-profile, shapeable, atraumatic, actuating distal blunt tip allows for microblunt dissection across a CTO.
Materials of Construction	- 304 Stainless Steel cutting tip - Nickel titanium (Nitinol) centering system component - Braided 304 stainless Steel catheter shaft with polymer jacket (polyether block amide polymer, Pebax) - Acrylonitrile Butadiene Styrene (ABS) Lustran Handle, with integrated 304 stainless steel torque wheel	N/A (unknown)
Packaging Configuration	- Die-cut SBS paperboard card - Tyvek Pouch (primary packaging, sterile barrier) - SBS Shelf Carton (secondary packaging, non-sterile)	Tyvek Pouch (primary packaging, sterile barrier)
Sterilization Method	- Electron Beam (E-Beam)	- Ethylene Oxide (EtO)

Design	Santreva-ATK consists of a tip, centering system, an outer catheter shaft, an inner torque cable tube with guidewire lumen, and a handle with integrated manually operated torque wheel and luer fitting for guidewire insertion. The distal catheter has a radiopaque rotating tip with an integrated cutting loop designed to puncture, displace, and compress the plaque as the mechanism of CTO crossing, which may facilitate formation of an angiographically visible channel, in combination with a centering system component to maintain luminal/intraplaque position. The centering system component has three collapsible wings which advance in the open lumen of the vasculature and within the CTO body, first to keep the loop/tip ensemble intraplaque, and second, to further dilate the initial channel formed by the tip. These collapsible centering system wings are sloped in each direction to present a tapered interface to both the CTO body plaque and to the support accessories such as guide catheters or guiding sheaths during advancement and retraction of the catheter. The catheter has a working length of 135 cm, with 1.35 mm (4.1 Fr) distal tip, 2.4 mm (7.2 Fr) centering system, and a 14 cm long handle.	The FRONTRUNNER CTO Catheter consists of a handle assembly with an integral rotator, a flush port, a flexible braided and integrated catheter shaft, and a radiopaque blunt-shaped distal actuating tip. The handle lever provides manual opening and closing of the distal tip, and the handle rotator provides rotational control for the shaft and distal tip. The FRONTRUNNER CTO Catheter features a 0.039-inch distal tip and crossing profile, and a 2.3-mm jaw opening allowing for microblunt dissection across a CTO. The peripheral catheter is available in lengths of 90cm and 140cm.

7. Performance Data

The following performance data were submitted to demonstrate the substantial equivalence of the Santreva-ATK device to the predicate device.

Biocompatibility Testing
Biocompatibility testing was performed on the final finished and sterilized Santreva-ATK device in compliance with ISO 10993-1 Biological evaluation of medical devices – Part 1. Biocompatibility testing included the following:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity: Systemic Injection
- Systemic Toxicity: Material Mediated Pyrogenicity
- Hemolysis: Complete (Direct & Indirect)
- Hemocompatibility: Partial Thromboplastin Time (PTT)
- Hemocompatibility: Complement Activation (SC5b-9)
- Thrombogenicity

Nonclinical Testing
The following nonclinical testing was performed on the Santreva-ATK device:

- Tensile
- Torque
- Tip Flexibility and Tip Load
- Flexibility and Kink Resistance
- Pushability and Pullability
- Sheath Compatibility
- Corrosion
- Particulate
- Radiopacity
- Dimensional Verification
- Guidewire Insertion and Functional Design Verification

Animal Testing
AngioSafe performed a GLP animal study with the Santreva-ATK device. The study evaluated the ability to navigate the Santreva-ATK device through small vessels and the overall safety of the devices, both during treatment and through histopathology evaluations, at sub-acute and chronic time points. These safety and performance evaluations of the Santreva-ATK device are compared with the FRONTRUNNER CTO Catheter (Control Device and predicate).

Two (2) groups of animals were treated, the subacute, 3-Day, Group 1 and the chronic, Group 2. For each point, both the Santreva-ATK and Control devices were used in each animal. Acute handling and performance of the Santreva-ATK and Control Devices were evaluated during the procedure. The Santreva-ATK devices performed comparably to the Control Devices for handling, performance, and safety endpoints supporting substantial equivalence to the predicate device.

Clinical Testing
The "Safety and Effectiveness Study of the AngioSafe Peripheral CTO Crossing System (RESTOR-1)" study was a prospective, single-arm, multi-center pivotal clinical trial designed to enroll subjects with a prior diagnosis of Peripheral Arterial Disease (PAD) and peripheral CTO at 14 study sites located in the United States. A sample size of 79 subjects had post-procedure data reviewed by the Core Laboratory (Full Analysis Set, FAS); this 79-subject population was used for safety analyses (Initial FAS and Safety Set n=79). Five (5) subjects were removed from the FAS due to protocol changes resulting in a final FAS population of 74 subjects (FAS n=74) used for effectiveness analyses. Four additional subjects were removed from the FAS for major protocol violations resulting in a Per Protocol (PP) analysis set of 70 subjects (PP n=70).

Primary Endpoint
Clinical Success of the Santreva-ATK device to facilitate placement of a guidewire into the distal true lumen of a femoropopliteal artery CTO, in the absence of device-related major adverse events (MAEs) through discharge or 24 hours post-procedure, whichever was sooner.

Results
The Santreva-ATK Endovascular Revascularization Catheter (referred to as the PER-2 device in the study) met its primary endpoint without device-related major or serious adverse events. Santreva-ATK demonstrated 87.8% clinical success rate in crossing femoropopliteal occlusions with 0.78 as lower bound of the 95% Confidence Interval in the Full Analysis (FAS) of n=74 study participants, and 90.0% clinical success rate in crossing femoropopliteal occlusions in the Per Protocol population of n=70 study participants with 0.80 as lower bound of the 95% Confidence Interval. Over 70% of the subjects in the FAS and PP datasets had CTOs with moderate to severely calcified plaques. Average treated CTO length was approximately 130 mm with a median crossing time of approximately 9 minutes, and mean crossing time of approximately 25 minutes. There were no device-related MAEs, such as major amputations, dissections, embolizations, or major perforations related to Santreva-ATK through discharge or 24-hours following the procedure, whichever was sooner. There was one (1) MAE within the 30 days following the procedure, which was neither procedure-related nor device-related.

Summary
Based on the clinical performance as documented in the RESTOR-1 pivotal clinical study (G200271), the Santreva-ATK device was found to have a substantially equivalent safety and effectiveness profile to the predicate device for its Intended Use/Indications for Use.

8. Substantial Equivalence Conclusion

The Intended Use and Indications for Use for the proposed Santreva-ATK device are the same as the predicate device. Differences in the technological characteristics between the proposed Santreva-ATK device and the predicate device do not raise any different questions of safety or effectiveness, as supported by submitted non-clinical, animal, and clinical testing data. Conclusions drawn from the non-clinical, animal, and clinical testing support the substantial equivalence of the Santreva-ATK device to the predicate device. Therefore, the Santreva-ATK device is substantially equivalent to the predicate device.