April 21, 2026

Sonorous NV, Inc.
% Erik Mulchandani
Quality Assurance & Regulatory Affairs Consultant
Global MedTech, LLC
1302 Scholarship
Irvine, California 92612

Re: K254046
Trade/Device Name: BosCATH Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: March 20, 2026
Received: March 20, 2026

Dear Erik Mulchandani:

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,

NAIRA MURADYAN -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254046

Device Name
BosCATH™ Support Catheter

Indications for Use *(Describe)*
The BosCATH™ Support Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The BosCATH™ Support Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The BosCATH™ Support Catheter is not intended for use in coronary arteries.

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:	April 20, 2026
Applicant:	Sonorous NV, Inc. 1 Spectrum Pointe Drive, Suite 150 Lake Forest, CA 92630
Applicant Contact:	Erik Mulchandani Quality Assurance & Regulatory Affairs Consultant (202) 246-0678
Device Name:	BosCATH™ Support Catheter
Regulation Number:	21 CFR 870.1250
Classification and Primary Product Code:	Class II, QJP (Catheter, Percutaneous, Neurovasculature)
Subsequent Product Code:	DQY (Catheter, Percutaneous)
Predicate Device:	SOFIA™ EX Intracranial Support Catheter (K230775)
Reference Device:	Navien™ Intracranial Support Catheter (K161152)

Device Description:
The BosCATH™ Support Catheter is a single-lumen catheter with variable stiffness and a hydrophilic coating to facilitate navigation through the vasculature. The catheter shaft is reinforced with a dual-layer construction of coil and braid wire, designed for providing enhanced support and flexibility. The distal end of the catheter incorporates one (1) or more radiopaque marker bands to aid in visualization under fluoroscopy. The inner lumen accommodates guidewires up to 0.038" in diameter, assisting in catheter placement. The proximal end of the catheter features a luer hub, allowing for the attachment of compatible accessories and the infusion of fluids as needed. The BosCATH™ Support Catheter is available in multiple lengths to accommodate physician preference and anatomical variability. The BosCATH™ Support Catheter is supplied sterile, non-pyrogenic, and intended for single use only. The BosCATH™ Support Catheter is supplied with a sterile introducer sleeve that is intended for single use only.

Indications for Use:
The BosCATH™ Support Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The BosCATH™ Support Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The BosCATH™ Support Catheter is not intended for use in coronary arteries.

Table 1: Comparison of Subject, Predicate and Reference Devices			
Attribute	SOFIA™ EX Intracranial Support Catheter Predicate Device (K230775)	Navien™ Intracranial Support Catheter Reference Device (K161152)	BosCATH™ Support Catheter Subject Device (K254046)
Indications for Use	The SOFIA EX Intracranial Support Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA EX Intracranial Support Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The SOFIA EX Intracranial Support Catheter is not intended for use in coronary arteries.	The Navien™ Intracranial Support Catheter is indicated for the introduction of interventional devices into the peripheral and neurovasculature.	The BosCATH™ Support Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The BosCATH™ Support Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The BosCATH™ Support Catheter is not intended for use in coronary arteries.
Primary Product Code	QJP	DQY	Same as K230775
Subsequent Product Code	DQY	N/A	Same as K230775
Regulation Number	21 CFR 870.1250	Same as K230775	Same as K230775
Design Feature(s)			
Tip	Straight	Same as K230775	Same as K230775
Dimensional Specifications			
Inner Diameter	0.058”	0.046” - 0.072”	Same as K230775
Outer Diameter	0.071”	0.058” - 0.084”	0.075”
Working Length (cm)	115	90 - 130	105 115 125
Materials			
Catheter Shaft	The outer layer consists of polyolefin elastomer, polyurethane elastomer (Pellethane), polyether	Polytetrafluoroethylene (PTFE) lined polymeric catheter	The outer layer consists of thermoplastic polyurethane (NEUsoft), polyether block amide (Pebax) and

Table 1: Comparison of Subject, Predicate and Reference Devices			
Attribute	SOFIA™ EX Intracranial Support Catheter Predicate Device (K230775)	Navien™ Intracranial Support Catheter Reference Device (K161152)	BosCATH™ Support Catheter Subject Device (K254046)
	block amide (Pebax) and polyamide (Grilamid). The inner layer consists of stainless-steel braid, Nitinol coil, and PTFE.		polyamide (Grilamid). The inner layer consists of stainless-steel coil/braid and PTFE.
Marker Band	Platinum/Iridium	Platinum	Same as K230775
Coating	Hydrophilic	Same as K230775	Same as K230775
Hub	Nylon	Not Specified	Polycarbonate
Strain Relief	Polyurethane	Not Specified	Polyether-based thermoplastic polyurethane
Introducer Sheath	Pebax	Not Specified	Same as K230775
Packaging			
Accessories	Introducer Sheath	Not Specified	Same as K230775
Configuration	The catheter is placed into a high-density polyethylene (HDPE) dispenser tube. The dispenser tube and introducer sheath are placed on a polyethylene packaging card that is inserted into a Tyvek® pouch. The pouch and the instructions for use are placed in solid bleached sulfate carton.	The catheter is placed into a polyethylene hoop that is attached to packaging card inside a polyethylene terephthalate (PET)/polyethylene (PE) Tyvek® pouch inside a solid bleached sulfate carton.	The catheter is placed into a combination packaging card/dispensing tube with the hub clipped into the packaging card. The combination packaging card/dispensing tube with the catheter and the introducer sleeve are sealed inside a DuPont™ TyveK® pouch. The sealed pouch and the instructions for use are placed into a solid bleached sulfate carton.
Stability			
Shelf Life	Not Specified	24 Months	12 Months
Sterility			
Sterilization Method	Ethylene Oxide	Same as K230775	Same as K230775

Performance Testing:

Packaging:

Test	Test Method Summary	Result
Visual Inspection	The packaging and labeling of the BosCATH™ Support Catheter was evaluated per ASTM F1886/F1886M-16.	Pass
Bubble Leak	The BosCATH™ Support Catheter packaging was evaluated per ASTM F2096-11 (2019).	Pass
Seal Strength	The BosCATH™ Support Catheter packaging was evaluated per ASTM F88/F88M-23.	Pass

Sterilization:

Test	Test Method Summary	Result
Ethylene Oxide Residual	The BosCATH™ Support Catheter was evaluated per ISO 10993-7:2008.	Pass
Ethylene Chlorohydrin Residual	The BosCATH™ Support Catheter was evaluated per ISO 10993-7:2008.	Pass
Bacterial Endotoxin Testing	The BosCATH™ Support Catheter was evaluated per United States Pharmacopeia, National Formulary, General Chapter <85> Bacterial Endotoxins Test.	Pass

Biocompatibility:

Biological Endpoint	Test	Test Method Summary	Results
Cytotoxicity	MEM Elution Cytotoxicity Assay (ISO)	The BosCATH™ Support Catheter was evaluated per ISO 10993-5:2009	Pass: The BosCATH™ Support Catheter was considered to be non-cytotoxic.
Sensitization	Guinea Pig Maximization Test (ISO)	The BosCATH™ Support Catheter was evaluated per ISO 10993-10:2021	Pass: The BosCATH™ Support Catheter was not considered a sensitizer.
Intracutaneous Reactivity	Intracutaneous Reactivity Test (ISO)	The BosCATH™ Support Catheter was evaluated per ISO 10993-23:2021	Pass: The BosCATH™ Support Catheter was considered a non-irritant.
Acute Systemic Toxicity	Acute Systemic Toxicity Test (ISO)	The BosCATH™ Support Catheter was evaluated per ISO 10993-11:2017	Pass: The BosCATH™ Support Catheter was

Biological Endpoint	Test	Test Method Summary	Results
			considered to be non-toxic.
Material-Mediated Pyrogenicity	Material Mediated Pyrogenicity Test (ISO/USP)	The BosCATH™ Support Catheter was evaluated per ISO 10993-11:2017 and USP-NF 2020: <151>	Pass: The BosCATH™ Support Catheter was considered to be non-pyrogenic.
Hemocompatibility	ASTM Hemolysis Assay (ISO)	The BosCATH™ Support Catheter was evaluated per ASTM F756-17 and ISO 10993-4:2017/A1: 2025	Pass: The BosCATH™ Support Catheter was considered to be non-hemolytic.
	Complement Activation Assay (ISO)	The BosCATH™ Support Catheter was evaluated per ISO 10993-4:2017/ A1:2025	Pass: The BosCATH™ Support Catheter was considered to be a non-activator of the complement system.
	A Non-Anticoagulated Venous Thrombogenicity Study in Ovine	The BosCATH™ Support Catheter was evaluated per ISO 10993-4:2017	Pass: Minimal thrombus formation was observed post-implantation of the BosCATH™ Support Catheter.

Performance Data – Bench:
The BosCATH™ Support Catheter was evaluated per ISO 10555-1, ISO 80369-7, ISO 80369-20 and FDA guidance documents "Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions" and "Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters - Class II Special Controls Guidance for Industry and FDA" for the following bench tests with passing results:

- Physical Attribute/Surface Contamination
- Simulated Use
- Dynamic Burst Pressure/Flow Rate
- Air Leakage
- Liquid Leakage
- Static Burst Pressure
- Tensile Strength
- Tip Flexibility
- Kink Resistance
- Torque Strength
- Corrosion Resistance
- Coating Lubricity
- Coating Durability
- Particulate
- Radiopacity
- Small-Bore Connectors

Performance Data – Animal:
The determination of substantial equivalence is based upon successful completion of bench performance testing.

Performance Data – Clinical:
The determination of substantial equivalence is based upon successful completion of bench performance testing.

Conclusion:
The subject BosCATH™ Support Catheter has the same intended use and similar technological characteristics as the predicate device SOFIA™ EX Intracranial Support Catheter. The differences between the subject device and predicate device do not raise new questions of safety and effectiveness. The conclusions drawn from device comparison and nonclinical testing conducted demonstrate that the subject device performs as intended and is substantially equivalent to the predicate SOFIA™ EX Intracranial Support Catheter.