November 9, 2024

S4 Medical Corp.
℅ Jennifer Daudelin
Director, MedTech Regulatory Affairs
ProPharma MedTech
1129 20th Street NW, Suite 600
Washington, District of Columbia 20036

Re: K243233
Trade/Device Name: esolution® Esophageal Retractor
Regulation Number: 21 CFR 870.5710
Regulation Name: Mechanical Deviation Device For Esophageal Protection During Cardiac Ablation Procedures
Regulatory Class: Class II
Product Code: QXU
Dated: October 9, 2024
Received: October 9, 2024

Dear Jennifer Daudelin:

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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243233

Device Name
esolution® Esophageal Retractor

Indications for Use *(Describe)*
The esolution® Esophageal Retractor is indicated for use in patients undergoing percutaneous cardiac catheter ablation of atrial fibrillation to deviate the esophagus away from the ablation energy source and to reduce the risk of ablation-related esophageal injury.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the S4 Medical Corp. 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

Sponsor: S4 Medical Corp.
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Chagrin Falls, OH 44022

Contact: Jennifer A. Daudelin, M.S.J.
ProPharma MedTech
1129 20th Street NW, Suite 600
Washington DC 20036
Ph: 347-954-0395
Email: jennifer.daudelin@propharmagroup.com

Date Prepared: October 7, 2024

Proposed Class: II

Proprietary Name: esolution® Esophageal Retractor

Common Name: Mechanical deviation device for esophageal protection during cardiac ablation procedures

Classification Name: Mechanical deviation device for esophageal protection during cardiac ablation procedures

Regulation Number: 21 CFR 870.5710

Product Codes: QXU

Predicate Device:

Manufacturer	Device Name	510(k) Number	Procode	Class
S4 Medical Corp.	esolution® Esophageal Retractor	DEN230006	QXU	II

Indications for Use

The esolution® Esophageal Retractor is indicated for use in patients undergoing percutaneous cardiac catheter ablation of atrial fibrillation to deviate the esophagus away from the ablation energy source and to reduce the risk of ablation-related esophageal injury.

Device Description

The esolution® Esophageal Retractor is a sterile mechanical deviation device for esophageal protection during cardiac ablation procedures. This device is placed in the lumen of the esophagus to reduce the likelihood of esophageal injury or a specific adverse event during cardiac ablation procedures. The device uses mechanical means to deviate the esophagus away from the source of ablation energy. The esolution® Esophageal Retractor contains two main components: an Outer Sheath, which is placed in the esophagus prior to the initiation of the therapeutic ablation procedure and a Mechanical Deflection Device that is inserted into the Outer Sheath once the Outer Sheath has been positioned in the esophagus for the indicated atrial fibrillation ablation therapeutic care. The purpose of this 510(k) is to capture the modifications made to the esolution® Esophageal Retractor required for manufacturability including changes to materials and design.

Performance Data – Non-Clinical

The modified esolution® Esophageal Retractor (Gen 2.1) has been evaluated through non-clinical performance testing. The esolution® (Gen 2.1) was tested for biocompatibility, tensile strength, deflection, and vacuum leak. The testing demonstrated that the esolution® (Gen 2.1) met performance requirements listed in the special controls and is substantially equivalent to the predicate device.

Technological Characteristics Comparison to Predicate Devices

Product Characteristic	Subject Device esolution (Gen 2.1)	Predicate Device esolution	Comparison
510(k) number	K243233	DEN230006	NA
Intended Use	The esolution® Esophageal Retractor is indicated for use in patients undergoing percutaneous cardiac catheter ablation of atrial fibrillation to deviate the esophagus away	The esolution® Esophageal Retractor is indicated for use in patients undergoing percutaneous cardiac catheter ablation of atrial fibrillation to deviate the esophagus away	Same – esolution Gen 2.1 has the same indications for use and intended use as the predicate esolution.

Product Characteristic	Subject Device esolution (Gen 2.1)	Predicate Device esolution	Comparison
	from the ablation energy source and to reduce the risk of ablation-related esophageal injury.	from the ablation energy source and to reduce the risk of ablation-related esophageal injury.	
Principle of operation	Mechanical esophageal retraction with suction	Mechanical esophageal retraction with suction	Same – no change
Major Components	Outer sheath and mechanical deflection device	Outer sheath and mechanical deflection device	Same – no change
Materials	ABS Silicone Stainless Steel 316 Polyvinyl chloride (PVC) Polypropylene Nylon 12 Polycarbonate Thermoplastic Elastomer	ABS Silicone Stainless Steel 316 Polyvinyl chloride (PVC) Polyurethane	Similar – new materials do not raise different questions of safety and effectiveness Biocomp 10993-1 repeated for Subject Device
Single Use	Yes	Yes	Same
Sterilization Method	Electron Beam Radiation	Electron Beam Radiation	Same
Sterilization Assurance Level (SAL)	10^{-6}	10^{-6}	Same
Biocompatibility	Meets requirements of ISO 10993-1 and "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" guidance document including: • Cytotoxicity • Irritation • Sensitization	Meets requirements of ISO 10993-1 and "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" guidance document including: • Cytotoxicity • Irritation • Sensitization	Same
Packaging	PETG Tray/ Blister with a sealed Tyvek lid.	PETG Tray/Blister in Single Tyvek pouch	Similar – different packaging configuration does not raise different

Product Characteristic	Subject Device esolution (Gen 2.1)	Predicate Device esolution	Comparison
			questions of safety and effectiveness
Device Insertion/ Withdrawal from cannula	Successful insertion/ withdrawal from cannula	Successful insertion/ withdrawal from cannula	Same
Tensile	Minimum strength of 15N	Minimum strength of 15N	Same
Deflection	Deflect and exert 0.7 lbf	Deflect and exert 0.7 lbf	Same
Vacuum Leak/ Decay Test	Maintain at least 200 mm Hg Vacuum when 300mmHg is applied	Maintain at least 200 mm Hg Vacuum when 300mmHg is applied	Same

Substantial Equivalence

The esolution® (Gen 2.1) has the same indications for use and similar design features as compared with the predicate device (DEN230006). The bench testing demonstrates that the performance characteristics of the esolution® (Gen 2.1) are equivalent to those of the legally marketed predicate device, and therefore supports a determination of Substantial Equivalence for the proposed indications for use. Any differences between the subject and predicate devices would not render the device NSE or raise different questions of safety and effectiveness.