September 6, 2023

S4 Medical Corp.
℅ Jennifer Daudlin
Senior Project Manager
M Squared Associates, Inc.
127 West 30th Street, 9th Floor
New York, New York 10001

Re: DEN230006
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: January 24, 2023
Received: January 24, 2023

Dear Jennifer Daudlin:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the esolution® Esophageal Retractor, a prescription device under 21 CFR Part 801.109 with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the esolution® Esophageal Retractor, and substantially equivalent devices of this generic type, into Class II under the generic name mechanical deviation device for esophageal protection during cardiac ablation procedures.

FDA identifies this generic type of device as:

> **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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On January 24, 2023, FDA received your De Novo requesting classification of the esolution® Esophageal Retractor. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the esolution into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the esolution® Esophageal Retractor can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Failure to protect the esophagus during ablation leading to esophageal perforating complications	Clinical performance testing Animal performance testing Non-clinical performance testing Labeling
Device malfunction leading to esophageal injury	Non-clinical performance testing Shelf life and packaging testing
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization validation Shelf life and packaging testing Labeling
Mechanical injury to esophageal or oral structures	Clinical performance testing Animal performance testing Labeling

In combination with the general controls of the FD&C Act, mechanical deviation device for esophageal protection during cardiac ablation procedures is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:
    (i) Evaluation of reduction of the incidence of esophageal injury during cardiac ablation procedures; and

(ii) Evaluation of any esophageal or oral injury from use of the device.

(2) Animal performance testing must demonstrate that the device performs as intended under the anticipated conditions of use and include the following:
   (i) Evaluation of the device's capability to adequately deviate the esophagus, including its trailing edge, away from the source of ablation energy; and
   (ii) Evaluation of any esophageal injury from use of the device.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:
   (i) Mechanical integrity testing using clinically relevant forces; and
   (ii) Compatibility testing with accessory devices.

(4) Performance data must demonstrate the sterility of any device components intended to be provided sterile.

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

(6) Performance data must support the shelf life of the device by demonstrating package integrity and device functionality over the identified shelf life.

(7) Labeling must include the following:
   (i) A summary of clinical performance testing with the device; and
   (ii) A shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the mechanical deviation device for esophageal protection during cardiac ablation procedures they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Vincent Do at 240-402-4584 or Vincent.Do@fda.hhs.gov.

Sincerely,

for William C. Macfarland -S

Digitally signed by William C. Macfarland -S
Date: 2023.09.06 17:15:31 -04'00'

Bram Zuckerman, M.D.
Director
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health