June 11, 2024

LSI SOLUTIONS, Inc.
Christopher Miller
Executive Director of Regulatory Affairs and Quality
7796 Victor-Mendon Road
Victor, New York 14564

Re: DEN230069
Trade/Device Name: Mi-CHORD System
Regulation Number: 21 CFR 870.3490
Regulation Name: Artificial chordae tendineae surgical replacement system
Regulatory Class: Class II
Product Code: SBK
Dated: September 28, 2023
Received: September 29, 2023

Dear Mr. Miller:

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 Mi-CHORD System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Mi-CHORD System is indicated for the replacement of adult mitral chordae tendineae with the patient on cardiopulmonary bypass, with the heart either arrested or fibrillating, and the surgical field under direct visualization.
>
> Direct visualization, in this context, requires that the surgeon is able to see the heart and target tissues in a bloodless field, with or without assistance from an operating telescope or videoscopy.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Mi-CHORD System, and substantially equivalent devices of this generic type, into Class II under the generic name artificial chordae tendineae surgical replacement system.

FDA identifies this generic type of device as:

> **Artificial chordae tendineae surgical replacement system**. An artificial chordae tendineae surgical replacement system is a standalone, prescription device consisting of nonabsorbable suture-based implant and suture placement device(s) that is used to replace mitral or tricuspid chordae tendineae in patients with atrioventricular valve insufficiency. The device includes clips or fasteners to secure the

suture that are not embedded in the cardiac tissue. The system is used via surgical approach under direct visualization and not via transcatheter or percutaneous access.

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 September 29, 2023, FDA received your De Novo requesting classification of the Mi-CHORD System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Mi-CHORD System 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 Mi-CHORD System 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**
Infection	Sterilization validation Shelf life testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Failure to deploy suture and/or anchor correctly (i.e. partial deployment, tangle, un-crimped, unable to cut/leave excess suture)	*In vivo* performance testing Non-clinical performance testing Simulated use testing Shelf life testing Labeling
Abnormal leaflet motion and/or coaptation, relapse of valvular regurgitation, loss of function	*In vivo* performance testing Labeling
Leaflet tearing; papillary muscle tearing	*In vivo* performance testing Non-clinical performance testing Labeling
Embolic events: thromboembolic; device emboli	*In vivo* performance testing Biocompatibility evaluation Labeling

Risks to Health	Mitigation Measures
Mechanical injury to coronary arteries or proximal tissues (e.g. native chordae)	*In vivo* performance testing Non-clinical performance testing Simulated use testing Labeling
Needle penetration through cardiac conduction system leading to postoperative arrythmias, including atrial fibrillation and heart block	*In vivo* performance testing Simulated use testing Labeling

In combination with the general controls of the FD&C Act, the artificial chordae tendineae surgical replacement system is subject to the following special controls:

(1) *In vivo* evaluation of the device must demonstrate that the device performs as intended under anticipated conditions of use. Testing must:
   (i) Demonstrate that the device performs as intended for atrioventricular valve repair;
   (ii) Demonstrate that the technology and techniques can be performed by the intended user population; and
   (iii) Evaluate all adverse events, including device malfunctions, tissue or vessel damage, unanticipated surgical interventions, and relapse of atrioventricular valve regurgitation.

(2) Simulated use testing must demonstrate the feasibility of device implantation and translatability to clinical use under worst-case clinical conditions, considering indicated anatomies, surgical access, and visualization.

(3) Non-clinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
   (i) Verification of diameters, tensile strengths, and bond or joint strengths of sterile suture components;
   (ii) Ability to orient the device appropriately to prevent damage to surrounding tissue structures;
   (iii) Consistency and reliability of implant deployment to achieve the desired treatment effect, including implant locations, leaflet tethering, and implant fixation;
   (iv) Mechanical integrity (e.g., tensile strength, fatigue or creep, bond failure) of the implant and placement devices to function under anticipated loading conditions;
   (v) Assessment of implant-tissue separation force;
   (vi) Durability of the implant;
   (vii) Compatibility of the implant in a magnetic resonance environment, if the implant contains magnetic or metallic materials; and
   (viii) Corrosion assessment, if the implant contains metal components.

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

(5) Performance data must validate the sterility of the patient-contacting components of the device.

(6) Performance data must support the shelf-life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.

(7) Labeling must include the following:
   (i) The recommended training for safe use of the device;
   (ii) A precaution to use clinical judgment in selecting patients eligible for atrioventricular valve surgery and suitable for the device;
   (iii) A precaution to maintain direct visualization of the tissues to be treated during use of the device;
   (iv) Identification of the maximum number of deployments and actuations for each device(s); and
   (v) 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 artificial chordae tendineae surgical replacement system 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 Kevin Soucy at 240-402-3682.

Sincerely,

for Kenneth J. Cavanaugh -S

Bram Zuckerman, M.D.
Director
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health