December 4, 2025

Chawla Heart Technologies LLC
℅ Semih Oktay
Founder, President
CardioMed Device Consultants LLC
3168 Braverton Street, Suite 200
Edgewater, Maryland 21037

Re: K252126
Trade/Device Name: MitraPatch™ Mitral Valve Repair System
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac Patch Or Pledget Made Of Polypropylene, Polyethylene Terephthalate, Or Polytetrafluoroethylene
Regulatory Class: Class II
Product Code: PAW
Dated: November 3, 2025
Received: November 3, 2025

Dear Semih Oktay:

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,

JULIE B. MACKEL -S

For

Jennifer Kevit, PhD
Acting Assistant Director
DHT2B: Division of Circulatory Support,
Structural, and Vascular Devices
OHT2: 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)*
K252126

Device Name
MitraPatch™ Mitral Valve Repair System

Indications for Use *(Describe)*
The MitraPatch is indicated to be used in the repair and replacement of marginal (primary) chordae tendinae only.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

Date Prepared	November 28, 2025
510(k) number	K252126
Applicant	Chawla Heart Technologies LLC 7 Seminole Way Bloomfield, CT 06002
Contact Person	H. Semih Oktay CardioMed Device Consultants LLC 1783 Forest Drive, Suite 254 Annapolis, MD 21401 Phone: 410-271-2088 Email:soktay@cardiomedllc.com
Proprietary Name	MitraPatch™ Mitral Valve Repair System
Common Name	Nonabsorbable expanded polytetrafluoroethylene surgical suture
Device Classification	Class II per 21 CFR §870.3470
Classification Name	Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture for Chordae Tendinae Repair or Replacement
Product Code	PAW
Predicate Device	On-X Life Technologies, Inc. Chord-X Pre-Measured Loops for Mitral Chordal Replacement (K141060)

Indication for Use:

The MitraPatch is indicated to be used in the repair and replacement of marginal (primary) chordae tendinae only.

Device Description:

The MitraPatch™ Mitral Valve Repair System includes a single use permanent implant designed to repair a mitral valve that is compromised due to chordae tendinea prolapse/rupture. Included in the system are a delivery handle and a locator tool. The MitraPatch™ fixes to the papillary muscle and mitral valve leaflet and providing a tension band between the two fixation points to prevent valve leaflet prolapse, replacing the natural function provided by the chordae tendinae.

One MitraPatch™ implant can repair one to two scallops of the mitral valve leaflets. MitraPatch™ is made from nonabsorbable expanded polytetrafluoroethylene (ePTFE) and is provided in a mono-membrane that is a nonabsorbable flexible material.

Comparison with Predicate Devices:

A comparison of the MitraPatch™ Mitral Valve Repair System (subject device) with the predicate devices shows that the technological characteristics of the subject device are the same, or similar, including the indication for use, principle of operation/mechanism of action, and method of sterilization.

In addition, the subject device treats the same anatomical location.

A tabular comparison of the subject and predicate device is provided below.

Device Name	**MitraPatch™**	**Chord-X Pre-Measured Loops for Mitral Chordal Replacement**
Device	**Subject Device**	**Predicate device**
Manufacturer	Chawla Heart Technologies LLC	On-X Life Technologies Inc
510(k) Number	K252126	K141060
Class/Product Code	Class II, PAW	
Regulation Number	21 CFR 878.3470	
Indications for Use	The MitraPatch is indicated to be used in the repair and replacement of marginal (primary) chordae tendinae only.	Chord-X Pre-Measured Loops for Mitral Chordal Replacement are indicated to be used in repair of replacement of chordae tendinae.
Anatomical Location	Mitral Valve	Mitral Valve
Implant Material	ePTFE	ePTFE
Mechanism of Action	Serves as a neochord to connect the distance between the papillary muscle and the leaflet to restore mitral valve function that is compromised due to a ruptured chordae	Serves as a neochord to connect the distance between the papillary muscle and the leaflet to restore mitral valve function that is compromised due to a ruptured chordae
Product Variants	1 size	Multiple loop sizes from 12=24mm, USP size 2-0 and 3-0 ePTFE sutures
Product Geometry	Mono membrane with attachment planes and holes for passing sutures	Monofilament
Needles	Not required	3/8 and ½ circular taper
Use of Plegets at tissue attachment locations	Yes, not provided with the device	Yes, provided with the device
Adjustable	Yes, if adjustment is desired the leaflet attachment can be released and adjusted to achieve the desired leaflet coaptation. Since the positioning of the implant is based on using a reference chord, and the length required is the same for all	The adjustment is performed at the leaflet attachment, location. The location of the suture that attaches the loop to the leaflet can be adjusted to the desired length of the loop that achieves level coaptation of leaflet surfaces.

Device Name	MitraPatch™	Chord-X Pre-Measured Loops for Mitral Chordal Replacement
	leaflets adjustment is not expected to be required to achieve level coaptation of leaflet surfaces	
Delivery or Other Accessories	Delivery Assist Tool and Locator Tool to assist in delivery	Measuring Device
How Supplied	Sterile, single use	Sterile, single use
Sterilization Method	EO	EO
Sterility Assurance Level	10^{-6}	10^{-6}

Non-Clinical Testing/Performance Data:

Non-clinical testing was performed on the MitraPatch™ Mitral Valve Repair System to support the substantial equivalence to the predicate device.

The following tests/assessments were performed:

- Tensile Strength
- Resistance to Creep
- Implant Capture Force
- Particulate
- Simulated Use
- Delivery System Clamping Bar Strength
- Sterilization- ISO 11135
- Shelf Life – ASTM 1980, ASTM 1929, ASTM 4169, ASTM F88

The in vitro bench tests demonstrated that the MitraPatch™ Mitral Valve Repair System met all acceptance criteria, functioned as intended and has a performance profile that is similar to the predicate device.

Biocompatibility

Biocompatibility evaluation of the MitraPatch™ Mitral Valve Repair System was performed. The following biocompatibility endpoints were assessed:

- Cytotoxicity- ISO 10993-5
- Sensitization – ISO 10993-10
- Intracutaneous Reactivity – ISO 10993-10
- Acute Systemic Toxicity – ISO 10993-11
- Hemocompatibility- ISO 10993-4
- Material Mediated Pyrogenicity – ISO 10993-11
- Genotoxicity – ISO 10993-3
- Chemical Characterization – ISO 10993-18
- Bacterial Endotoxin – USP <85>

Preclinical Animal Testing Summary

Subchronic animal study whereby the MitraPatch device was used to repair a ruptured (severed) chordae tendinae. There was no evidence of inflammation, migration or deterioration of the implant, There were no abnormal histopathological findings. Substantially equivalent device performance, stability, and biological safety were demonstrated.

Conclusion

The MitraPatch™ Mitral Valve Repair System has the same intended use and the same, or similar, technological characteristics as the predicate device. None of the differences between the subject and predicate devices raises any new questions or safety or effectiveness.

The conclusions drawn from the non-clinical tests exhibit that the MitraPatch™ Mitral Valve Repair System demonstrate substantially equivalent safety and effectiveness outcomes to the predicate device.