December 21, 2021

Helios Cardio Inc.
% Roshana Ahmed, President
Quaras, LLC
2101 Camino Rey
Fullerton, California 92833

Re: K210331
Trade/Device Name: CardiaMend™ Pericardial and Epicardial Reconstruction Matrix
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: PSQ
Dated: November 23, 2021
Received: November 24, 2021

Dear Roshana Ahmed:

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 (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 located 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.

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 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Rachel Neubrander
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210331

Device Name

CardiaMend™ Pericardial and Epicardial Reconstruction Matrix

Indications for Use *(Describe)*

CardiaMend™ Pericardial and Epicardial Reconstruction Matrix is intended for pericardial reconstruction and repair and for epicardial support and repair.

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.

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510(k) Summary

I. Submitter

Helios Cardio Inc.
11 Dellbrook Road
Weston MA 02493
Phone: (617) 818-4008
Fax: N/A

Contact Person: Yiannis Monovoukas, President & CEO
Date Prepared: December 17, 2021

II. Device

Device Proprietary Name:	CardiaMend™ Pericardial and Epicardial Reconstruction Matrix
Common or Usual Name:	Intracardiac Patch
Classification Name:	Intracardiac Patch Or Pledget Made Of Polypropylene, Polyethylene Terephthalate, Or Polytetrafluoroethylene
Regulation Number:	21 CFR 870.3470
Product Code:	PSQ
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- CorMatrix® Cor Patch, K181038, CorMatrix Cardiovascular, Inc.
- CorMatrix Pericardial Patch (currently marketed as ProxiCor for Pericardial Closure by Aziyo Biologics, Inc.), K051405, CorMatrix Cardiovascular, Inc.

The following devices are cited as reference devices within the submission:

- SurgiMend™ Collagen Matrix for Soft Tissue Reconstruction, K071807, TEI Biosciences Inc.
- Durepair Dura Regeneration Matrix, K041000, Medtronic Neurosurgery

IV. Device Description

CardiaMend™ Pericardial and Epicardial Reconstruction Matrix is a porous acellular matrix derived from fetal bovine dermis designed to provide soft tissue reinforcement, repair, and reconstruction. The single-layer (1 ply) device is not chemically crosslinked and consists of a naturally woven network of collagen fibers.

The single use device is supplied terminally sterilized via ethylene oxide and is available in a variety of sizes to be trimmed by the physician to meet individual patient needs. The following sizes are provided:

- 4 x 7 cm (thickness 0.40 – 0.75 mm)
- 5 x 6 cm (thickness 0.75 – 1.54 mm)
- 6 x 12 cm (thickness 0.75 – 1.54 mm)
- 8 x 12 cm (thickness 0.40 – 0.75 mm)
- 8 x 16 cm (thickness 0.75 – 1.54 mm)
- 10 x 15 cm (thickness 0.75 – 1.54 mm)

V. Indications for Use

CardiaMend™ Pericardial and Epicardial Reconstruction Matrix is intended for pericardial reconstruction and repair and for epicardial support and repair.

VI. Technological Characteristics

The technological characteristics of CardiaMend™ Pericardial and Epicardial Reconstruction Matrix are substantially equivalent to the cleared CorMatrix® Pericardial Patch (K051405) and CorMatrix Cor Patch (K181038). A comparison of the devices is provided in the table below.

	CardiaMend™ Pericardial and Epicardial Reconstruction Matrix	**CorMatrix® Cor Patch (K181038)**	**CorMatrix Pericardial Patch (K051405; marketed as ProxiCor for Pericardial Closure)**	**Analysis**
Indications for Use	Pericardial reconstruction and repair, and epicardial support and repair.	The CorMatrix Cor Patch is intended for epicardial tissue support and repair.	The CorMatrix Pericardial Patch is intended for the reconstruction and repair of the pericardium.	Same

	CardiaMend™ Pericardial and Epicardial Reconstruction Matrix	**CorMatrix® Cor Patch (K181038)**	**CorMatrix Pericardial Patch (K051405; marketed as ProxiCor for Pericardial Closure)**	**Analysis**
Reusable or single use	Rx Only, Single-Use	Rx Only, Single-Use	Rx Only, Single-Use	Same
Material Type	Collagen, Extracellular Matrix	Collagen, Extracellular Matrix	Collagen, Extracellular Matrix	Same
Animal Tissue Source	Fetal bovine dermis	Porcine small intestinal submucosa (SIS)	Porcine small intestinal submucosa (SIS)	Different
Chemical Crosslinking	No	No	No	Same
Acellular	Yes	Yes	Yes	Same
Resorbable	Yes	Yes	Yes	Same
Shape	Rectangular sheet	Rectangular sheet	Rectangular sheet	Same
Size(s)	• 4 x 7 cm • 5 x 6 cm • 6 x 12 cm • 8 x 12 cm • 8 x 16 cm • 10 x 15 cm	• 4 x 7 cm • 7 x 10 cm	• 7 x 10 cm • 7 x 15 cm	Different
Number of Layers	Single-ply	Multi-ply	Multi-ply	Different
Thickness	0.4 – 0.75 mm and 0.75 – 1.54 mm	~0.4 mm	~0.4 mm*	Different
Rehydration	Room temperature sterile saline	Room temperature sterile saline	Room temperature sterile saline	Same
Sterilization	Ethylene oxide	Ethylene oxide	Ethylene oxide	Same
Storage	Store dry, at room temperature	Store dry, at room temperature	Store dry, at room temperature	Same
Biocompatibility	ISO 10993	ISO 10993	ISO 10993	Same

**as reported in the literature.*

As seen in the table above, the primary differences between the subject and predicate device are the animal tissue source, the available product sizes, number of layers, and thickness. These differences do not raise different questions of safety and effectiveness, and substantial equivalence to the predicate devices is demonstrated through verification and validation studies.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination:

- Sterilization validation/re-qualification
- EO/ECH residuals per ISO 10993-7
- Packaging validation and shelf-life per ISO 11607-1 and ISO 11607-2
- Device Characterization Testing
    - Dimensional verification
    - Tensile Strength
    - Tensile Stiffness/Elastic Modulus
    - Burst Strength
    - Suture Pullout Strength
    - Cellular Infiltration
    - Porosity
    - Collagen Denaturation
- Design Validations
    - Usability Validation
- GLP Study in an Ovine Model
    - The performance and safety of CardiaMend™ Pericardial and Epicardial Reconstruction Matrix was evaluated in an ovine model compared to the predicate device, CorMatrix Pericardial Patch (K051405; marketed as ProxiCor for Pericardial Closure).
    - All study objectives were met. The sheep did not exhibit any test article-related abnormalities throughout the study. At the completion of the study, all animals survived and were evaluated as being in excellent health. There were no adverse events in any of the animals.

In addition, existing viral inactivation, sterilization validation, and biocompatibility data were leveraged from the reference SurgiMend™ Collagen Matrix for Soft Tissue Reconstruction (K071807) device, as the subject and reference devices are identical in material source, thickness, manufacturing, sterilization processes, and packaging.

VIII. Conclusion

The subject device design was evaluated through biocompatibility, animal studies, and other performance testing to provide evidence of safe and effective use of CardiaMend™ Pericardial and Epicardial Reconstruction Matrix. CardiaMend™ Pericardial and Epicardial Reconstruction Matrix is substantially equivalent to the specified predicate devices based on comparisons of device functionality, technological characteristics, and indications for use.