March 20, 2025

CardioVia Ltd.
Orly Maor
Company Regulatory Consultant
Wadi El Haj, 13, P.O. Box 1252
Nazareth, 17111
Israel

Re: K243928
Trade/Device Name: ViaOne Epicardial Access System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: December 16, 2024
Received: December 20, 2024

Dear Orly Maor:

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)*
K243928

Device Name
ViaOne Epicardial Access System

Indications for Use *(Describe)*
The ViaOne Epicardial Access System is intended to access the epicardial surface of the heart via a subxiphoid approach to deliver diagnostic and therapeutic interventions for ventricular tachycardia.

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.

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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

Traditional Premarket Notification Submission – 510(k)
ViaOne Epicardial Access System
510(k) Number K243928

Date Prepared: March 20, 2025

I. SUBMITTER
CardioVia Ltd.
Wadi El Haj, 13, P.O. Box 1252
17111 Nazareth, Israel
M: +(972) 524807162
T: +(972) 46098609
W: www.cardiovia.com

Contact Person
Orly Maor
25 Sirkin Street
Kfar Saba 44421 Israel
Tel: +972-9-7453607
oram.ma@gmail.com

II. DEVICE
Name of Device: ViaOne Epicardial Access System
Common or Usual Name: ViaOne
Classification Name: Introducer, Catheter
Regulatory Class: Class II, per 21 CFR 870.1340
Product Code: DYB.
Classification Panel: Cardiovascular

III. PREDICATE DEVICE
CardioVia Ltd. believes that the ViaOne Epicardial Access System, which is the subject of this premarket notification, is substantially equivalent to the following predicate device:

- AtriCure, Inc. EPi-Ease™ Epicardial Access System (EAS) cleared under K233959 (product code DYB Regulation No. 21 CFR 870.1340).

IV. DEVICE DESCRIPTION
ViaOne Epicardial Access System is a sterile, single-use access tool consisting of a concealed needle within a leading channel to facilitate guidewire access into the pericardium through a subxiphoid incision. The device consists of a radiopaque distal tip designed to retract a portion of the pericardial tissue into the device, and away from the heart muscle, where it is punctured by the concealed needle and a guidewire is introduced into the pericardial space.

V. INDICATIONS FOR USE

The ViaOne Epicardial Access System is intended to access the epicardial surface of the heart via a subxiphoid approach to deliver diagnostic and therapeutic interventions for ventricular tachycardia.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

ViaOne Epicardial Access System has the same intended use as the predicate device. Its indications for use are identical to that of the predicate device. The ViaOne Epicardial Access System has similar technological characteristics to the predicate device as demonstrated in the table below.

Feature	**Proposed: ViaOne Epicardial Access System**	**Predicate: EPi-Ease™ Epicardial Access System (EAS)**	**SE Justification**
510(k) Number	K243928	K233959	___
Manufacturer	CardioVia Ltd.	AtriCure, Inc.	___
Product Code	DYB	DYB	**Same**
CFR	21 CFR 870.1340	21 CFR 870.1340	**Same**
Intended Use	The ViaOne Epicardial Access System is intended to access the epicardial surface of the heart via a subxiphoid approach to deliver diagnostic and therapeutic interventions for ventricular tachycardia.	The EPi-Ease™ Epicardial Access System is intended to access the epicardial surface of the heart via subxiphoid approach.	**Same** Within the predicate scope (The indication was confirmed under FDA's Breakthrough Device Designation)
Access	Sub-xiphoid	Sub-xiphoid	**Same**
Needle size and Devic profile	17.5 Ga. Needle (similar to Tuohy – 17 Ga.) 11 Fr. device profile	22 Ga. Tuohy needle 18 Fr. device profile	**Similar** ViaOne device profile is 2/3 of the predicate and the smaller needle diameter has no impact on safety as it is concealed and intended to puncture the pericardium within the tube
Visualization	Fluoroscopy required. Endoscopic visualization-Not required	Fluoroscopy Required. Endoscopic visualization-Optional	**Same**

Feature	Proposed: ViaOne Epicardial Access System	Predicate: EPi-Ease™ Epicardial Access System (EAS)	SE Justification
Tissue retraction	Engagement element enable retraction	Vacuum enable retraction	**Different** Although capturing of the tissue is performed differently it brings the same result of inserting the pericardium into a sealed compartment
Radiopaque marker	Yes—distal tip	Yes—distal tip	**Same**
Operating Principles	Advancement through adipose tissue to reach pericardial sac, needle punctures pericardial sac, guidewire advances through needle into pericardial sac, introducer advances over guidewire and pre- dilates pericardial sac, sheath advances over guidewire into pericardial sac to access epicardial surface of the heart. Needle advancement limits to mitigate risks associated with the predicate.	Advancement through adipose tissue to reach pericardial sac, needle punctures pericardial sac, guidewire advances through needle into pericardial sac, introducer advances over guidewire and pre- dilates pericardial sac, sheath advances over guidewire into pericardial sac to access epicardial surface of the heart. Needle advancement limits to mitigate risks associated with the predicate.	**Same**
Reuse	Single Use.	Single Use.	**Same**
Environments of Use	OR with imaging equipment, including fluoroscopy under sterile technique.	OR with imaging equipment, including fluoroscopy under sterile technique.	**Same**
Sterilization	Sterile for single use (EtO).	Sterile for single use (EtO).	**Same**

VII. PERFORMANCE DATA

The following performance data were conducted. The ViaOne Epicardial Access System met the predetermined acceptance criteria ensuring substantial equivalence to the predicate. No new safety or effectiveness issues were raised during testing:

- **Biocompatibility**

  Biocompatibility evaluation in compliance with ISO 10993-1 was performed.
  The following tests were conducted:
  - Cytotoxicity Study - ViaOne
  - Cytotoxicity Study - fluid path
  - ISO Intracutaneous /irritation Study
  - Sensitization Test
  - Acute Systemic Toxicity Study
  - Pyrogen Study - Material Mediated Study

  All tests were successfully completed and passed, and the device met the defined acceptance criteria and was found to be biocompatible.

- **Sterilization, Packaging and Shelf Life Testing**

  Sterilization validation was performed to demonstrate compliance with ISO 11135-1. In addition, transportation simulation and environmental tests prior to real-time shelf life that included packaging testing and performance to support the one year labeled shelf life.

  All tests were successfully completed and passed, and the device met the defined acceptance criteria.

- **Performance Testing**

  Performance testing included the following:
  - Simulated Use
  - Dimensions
  - Visual inspection surface analysis
  - Spring force
  - Tensile Strength
  - Radiopacity
  - Corrosion
  - Engagement element functionality
  - Verification testing, following ISO 11070:2014 standards including:
    - Outer tube surface analysis
    - Outer tube rim analysis
    - Laser-cut flower shaft & outer tube rim inspection

  All tests were successfully completed and passed, and the device met the defined acceptance criteria.

- **Animal Study**
  Animal Study evaluated the ViaOne Epicardial Access System safety and performance. The devices performed as intended without malfunction. The Histopathology evaluation and pathological examination indicated that there were no severe or clinically significant events following use of the ViaOne Epicardial Access System.

- **Clinical Information**
  CardioVia provided information on clinical experience from its multi-central clinical trial which included VT subjects. The primary endpoint of the clinical study focused on the occurrence and resolution of adverse events associated with the ViaOne device.
  The secondary endpoint of the clinical study evaluated the success rate of pericardial space access. The observed adverse events were consistent with those expected in similar epicardial procedures and were resolved without additional intervention. The collected clinical data demonstrated a safety profile consistent with established standards and demonstrates that the ViaOne Epicardial Access System supports its intended use in the indicated population.

VIII. CONCLUSIONS

CardioVia has demonstrated that the ViaOne Epicardial Access System is substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principal, and intended use/ indication for use to the predicate device, the EPi-Ease Epicardial Access System.