June 25, 2025

Kardium Inc.
Ricardo Romero
Vice President, RA&QA
8518 Glenlyon Parkway, Unit 155
Burnaby, BC V5J OB6
Canada

Re: K250747
Trade/Device Name: Globe® Pulsed Field System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK
Dated: March 11, 2025
Received: March 12, 2025

Dear Ricardo Romero:

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.

Submission Number *(if known)*

K250747

Device Name

Globe® Pulsed Field System

Indications for Use *(Describe)*

The Globe PF System is indicated for catheter-based cardiac anatomical and electrophysiological mapping and stimulation of cardiac tissue.

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

per 21 CFR §807.92

Date Summary Prepared	June 24th, 2025
Applicant	Kardium Inc. 155-8518 Glenlyon Parkway Burnaby, British Columbia V5J 0B6 Canada
Official Correspondent	Ricardo Romero Vice President, RA&QA Kardium Inc. Tel: +1 604.248.8891
510(k) Number	K250747
Device Trade Name	Globe® Pulsed Field System
Common Name	Globe Pulsed Field System
Classification Name	Computer, Diagnostic, Programmable
Classification	Class II, 21 CFR Part 870.1425, Cardiovascular
Product Code	DQK
Predicate Device	Affera Integrated Mapping System; Impedance Localization Patch Kit (K241828)
Reference Device	Swan-Ganz Catheter (K160084)
Device Description	The Globe Pulsed Field System (Globe PF System) comprises the following components and accessories to support anatomical and electrophysiological mapping, and pacing stimulation of cardiac tissue: • Globe Controller: Used for the acquisition and processing of signals for cardiac anatomical and electrophysiological mapping, generation of mapping energy and stimulation pulses. • Globe Workstation: A PC workstation configured with the Globe Software, which the clinician uses to assess contact between the mapping catheter electrodes and the atrial wall, map the atrial electrical activity, and apply stimulation pulses for diagnostic purposes. • Globe Positioning System (GPS™) Electrodes and GPS Cable: Surface electrodes and cables for localization of the mapping catheter.

Intended Use	Catheter-based electrophysiological mapping and stimulation.
Indications for Use	The Globe PF System is indicated for catheter-based cardiac anatomical and electrophysiological mapping and stimulation of cardiac tissue.
Comparison of Technological Characteristics	A comparative overview of the subject and predicate device is provided in the following table:

Attribute	Affera Mapping System (K241828)	Subject Device: Globe® PF System (K250747)
Mapping System		
Intended Use	Catheter-based electrophysiological mapping and stimulation.	Same
Fundamental Scientific Technology (Navigation/ localization)	• Impedance-based tracking • Magnetic-based tracking	• Impedance-based tracking
Key System Components	• Catheter/equipment interface unit (CIU) • Workstation and software • Magnetic field generator	• Globe Controller • Globe Workstation and software
Electroanatomical Maps	3D geometric shell, voltage, impedance, activation, and propagation maps.	3D geometric shell, voltage, impedance, contact, activation, and propagation maps.
Stimulation/ Pacing	Internally (20mA max) and externally generated pacing.	Internally (10mA max).
ECG Signal Acquisition	Body surface ECG signals recorded directly by the Affera Integrated Mapping System.	Same
EGM Acquisition	Intracardiac electrogram signals measured by the catheter's electrodes.	Same
Globe Positioning System (GPS) Electrodes and Cable		
Configuration	6 surface electrodes/patches.	• 6 surface electrodes/patches (GPS Electrodes) • Adapter cable (GPS Cable)

Attribute	Affera Mapping System (K241828)	Subject Device: Globe® PF System (K250747)
Supported Tracking and Navigation Modalities	• Impedance-based tracking • Magnetic-based tracking	• Impedance-based tracking
Electrode Sterility	Non-sterile	Same
Electrode Use Limitations	Single-use	Single-use

The Globe PF System shares the following identical or similar intended use and technological characteristics with the predicate device:

- Same intended use.
- Equivalent indications for use. Both systems are indicated for catheter-based cardiac electrophysiological mapping and stimulation (pacing). The additional details on the technological characteristics provided by the predicate system are explanatory and do not affect the equivalence.
- Both devices include impedance-based tracking of compatible catheters.
- Both devices utilize a central interface unit for connection with a workstation, and compatible catheters.
- Both devices include proprietary software designed to present the user with information regarding the location of the mapping catheter and electroanatomical maps (3D geometric shell, voltage, impedance, activation, and propagation maps).
- Both devices have the capability to directly acquire ECG and electrogram signals.
- Both devices have the capability to deliver stimulation.
- The GPS electrodes and cable are equivalent to the predicate's localization kit. The GPS cable is an electrical extension of the surface electrodes that does not introduce new technological characteristics.

The differences in technological characteristics are as follows:

- The Globe PF System is intended for impedance-based tracking of catheters, whereas the predicate device includes impedance-based and magnetic-based tracking.

	• The Globe PF System can deliver stimulation from an internal source, whereas the predicate device can deliver stimulation for an internal and external source. • The Globe PF system includes additional electroanatomical maps; contact maps (FLOW™ and CONTACT™). The delivery of thermal energy to tissue and sensing of the resulting thermal response used for the Globe PF System's CONTACT and FLOW maps are based on the same principles of operation as the reference device (Swan-Ganz catheter, K160084). Since the reference device is used in the same anatomical location, and the energy delivery and sensing methods have the same principles of operation, the scientific methods used to evaluate the safety and effectiveness of the CONTACT and FLOW mapping functionality of the Globe PF System are adequate. These differences do not raise different questions of safety and effectiveness and do not preclude a meaningful comparison with the predicate devices.
Safety and Performance Data	The following performance testing was conducted to support the Globe PF System: • Bench testing • Biocompatibility testing • Summative usability testing • Electrical safety and EMC testing • Software verification and validation testing • Cybersecurity testing • Packaging validation Testing was performed following the applicable principles and recommendations of relevant FDA-recognized consensus standards and guidance documents. The test results demonstrate that the Globe PF System meets the performance criteria for its intended use and does not raise new questions on safety or effectiveness compared to the predicate device.
Statement of Equivalence	The Globe PF System and predicate device have identical or equivalent intended use, indications for use, and performance. Differences in technological characteristics do not raise any new or different questions of safety and effectiveness. Based on this and the results of performance testing, the Globe PF System is substantial equivalent to the predicate device.

Disclaimer: All information provided herein, including comparisons of the Globe PF System with other products, is provided for the purpose of a 510(k) premarket notification and has no bearing on and has not been provided in view of any national or international patent laws, including Title 35 of the United States Code, for which different analyses apply.