June 3, 2025

Kardium Inc.
Ricardo Romero
Vice President, RA&QA
8518 Glenlyon Parkway, Unit 155
Burnaby, BC V5J 0B6
Canada

Re: K250529
Trade/Device Name: Globe® Introducer
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: Class II
Product Code: DRA
Dated: May 5, 2025
Received: May 6, 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.

510(k) Number *(if known)*
K250529

Device Name
Globe® Introducer

Indications for Use *(Describe)*
The Globe Introducer is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart, including the left side of the heart through the interatrial septum.

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.

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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."

Kardium

510(k) Summary

per 21 CFR §807.92

Sponsor	Kardium Inc. 155-8518 Glenlyon Parkway Burnaby, British Columbia V5J 0B6 Canada
Contact Name and Information	Ricardo Romero Vice President, RA&QA Kardium Inc. Tel: +1 604.248.8891
Date Prepared by	February 21st, 2025
Proprietary Name	Globe® Introducer
Common Name	Steerable catheter
Product Code	DRA
Classification	Class II, 21 CFR Part 870.1280
Predicate Device	FARADRIVE™ Steerable Sheath (K233248)
Device Description	The Globe® Introducer is a single use, ethylene oxide sterilized medical device used to facilitate percutaneous access to the vasculature and into the heart chambers. The device consists of a 16 Fr (5.3 mm) inner diameter (ID) steerable sheath with a hydrophilic coating, a dilator compatible with 0.89 mm (0.035 in) guidewires, and a dilator loader. The proximal end of the sheath includes a handle with an integrated steering knob for bidirectional deflection control of the sheath tip, a steering indicator, and a slider. The slider contains a loader connection port for the dilator loader and a compatible catheter loader. The slider provides a hemostatic seal and a saline flushing line with a standard Luer fitting stopcock, for air removal and management.
Indications for Use	The Globe Introducer is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart, including the left side of the heart through the interatrial septum.

Predicate Comparison

Table 1: Comparison of Technological Characteristics with the Predicate Device

Characteristics	Subject Device: Globe® Introducer	Predicate Device: FARADRIVE™ Steerable Sheath (K233248)	Comparison
Product Code	DRA	DRA	Identical
Intended Use / Indications for Use	The Globe Introducer is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart, including the left side of the heart through the interatrial septum.	The FARADRIVE Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart, including the left side of the heart through the interatrial septum.	Same Intended Use / Indications for Use
Design Features	Steering knob that rotates in the plane of the handle	Actuator knob that rotates coaxially to the handle	Differences in the steering mechanism do not alter the fundamental scientific technology or pose an added safety risk.
	Bi-directional shaft deflection clockwise ≥90° counterclockwise ≥45°	Unidirectional shaft deflection from 0°to 180°	The range of motion has been shown to be sufficient for anatomical placement of compatible catheters. The differences do not raise new questions of safety or effectiveness.
	Integrated hemostatic seal, slider port, and flush line with three-way stopcock	Integrated hemostasis valve and side flush line with three-way stopcock	The differences in design do not alter the fundamental scientific technology or raise new questions about device performance or safety.

	Distal vent holes	Distal vent holes	Same design characteristics
	Radiopaque tip marker	Radiopaque tip marker	Same design characteristics
Dimensions	Sheath size: – Inner diameter: 16 F – Usable length: 71 cm – Sheath outer diameter: 21 F	Sheath size: – Inner diameter: 13 F – Usable length: 74 cm – Sheath outer diameter: 17.4 F	The differences in sheath dimensions ensure compatibility with prescribed catheters under identical intended uses of the sheath.
	Dilator size: – Dilator usable length: 102 cm (40.24 in) – Dilator inner diameter: 0.9 mm (0.035 in) – Dilator outer diameter: 5.2 mm (0.205 in)	Dilator size: – Dilator usable length: 94 cm (36.85 in) – Dilator inner diameter: 0.9 mm (0.037 in) – Dilator outer diameter: 4.4 mm (0.172 in)	The differences in dilator dimensions do not alter the fundamental scientific technology nor do they raise new questions about device performance or safety.
Guidewire Compatibility	Maximum diameter: 0.89 mm (0.035 in)	Maximum diameter: 0.89 mm (0.035 in)	Same guidewire compatibility.
Materials	This device contains: – Hydrophilic coated (polyvinylpyrrolidone) polyether block amide (PEBAX) – Nylon – Polytetrafluoroethylene (PTFE) liner – Silicone rubber – Polycarbonate – Polyethylene – Polyvinyl Chloride (PVC) – Acetal – Rilsan	This device contains: – Polyether block amide (PEBAX) – Nylon – Stainless steel – Hydrophilic coated PEBAX liner – Silicone rubber – Polycarbonate – Polyethylene	The subject and predicate devices are constructed of equivalent materials. Any differences have been qualified through biological safety and performance testing.
Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Same sterilization method.

Single Use	Yes	Yes	Same limitations on use.
Packaging	Tyvek nylon/polyethylene pouch with a protective tray	Tyvek nylon/polyethylene pouch	Same sterile barrier system. Minor differences in packaging do not raise new questions about device performance or safety, as demonstrated by pre-clinical and packaging validation testing.

Non-clinical Performance Data

The following testing was conducted to support the determination of substantial equivalence between the Globe Introducer and the predicate device:

- Biocompatibility Testing
- Sterilization Validation
- Packaging Validation
- Shelf-Life Testing
- Bench Testing
    - Particulate Test
    - Deployment-Retraction Force Test
    - Flushing Test
    - Pressure Withstand Test
    - Corrosion Resistance Test
    - ISO 80369 Luer Test
    - Introducer Health Check Test
    - Dimensional Inspection Test
    - Steering Knob Torque Test
    - Sheath Tensile Test
    - Mechanical Performance Test
    - Torque Test
    - Lubricity Test
    - Radiopacity Test
    - Dilator Performance Test
    - Air Egress Test

Bench 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 Introducer 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 Introducer and predicate device have identical or equivalent intended use, indications for use, technological characteristics, and performance. Differences in design do not raise any new or different questions of safety and effectiveness. Based on this and the results of performance testing, the Globe Introducer is substantial equivalent to the predicate device.