October 21, 2025

Cardiocycle Medical (Suzhou) Co.,Ltd.
Unit 401&501, Building C15, Stage 5, BioBAY, No.21
Chaoqian Road, Suzhou Industrial Park
Suzhou, China 215000

Re: K251838
Trade/Device Name: Introducer Sheath Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: September 23, 2025
Received: September 23, 2025

Dear Ling Li:

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, FINN E. DONALDSON -S

Digitally signed by FINN E. DONALDSON -S
Date: 2025.10.21 08:12:52 -04'00'

Finn Donaldson
Team Lead
DHT2C: Division of Coronary and
Peripheral Intervention 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)*
K251838

Device Name
Introducer Sheath Set

Indications for Use *(Describe)*
The Introducer Sheath set is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

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

510(k) Owner:

Cardiocycle Medical (Suzhou) Co.,Ltd.
Unit 401&501, Building C15, Stage 5, BioBAY, No.21
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Date Prepared: September 23, 2025

Device Names/Classification:

Trade Name:	**Introducer Sheath Set**
510(k) Number:	K251838
Product code:	DYB
Regulation:	21 CFR 870.1340
Classification panel:	Cardiovascular
Device class:	Class II
Predicate Device:	GORE® DrySeal Flex Introducer Sheath Set

1. Device description

The Introducer Sheath Set consists of a sheath and a dilator. The sheath is comprised of a sheath tube, a sheath hub, and a hemostatic valve. While the dilator comprises a dilator hub, a dilator tube and a rod cap. The sheath features a hydrophilic coating. Each set of products is equipped with a sheath and a dilator. The product is sterilized with ethylene oxide and is disposable.

2. Indication for use

The Introducer Sheath set is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

3. Comparison to the predicate device

The intended use and indications for use for the Introducer Sheath device are identical to the predicate GORE® DrySeal Flex Introducer Sheath Set. The main differences between the subject and predicate devices is that the Introducer Sheath Set does not contain a syringe and has less model specifications than the predicate device.

4. Performance testing

The subject device was evaluated by the following performance testing to support its substantial equivalence to the predicate device:

- Dimensions
- Appearance
- Radio-detectability
- Distal Tips
- Hub
- Hydrophilic Coating Integrity
- Hydrophilic Coating Lubricity
- Leakage
- Mechanical Requirements: Tensile Force
- Simulated-use test in Arterial Vessel Model and Venous Vessel Model: Compatibility, Guidewire Trackability, Pushability Performance, Withdrawal Performance, Resistance Performance, Kink Resistance Performance
- Sterility
- Bacterial Endotoxin
- Packaging validation
- Biocompatibility:
    - Cytotoxicity

- Sensitization
- Irritation
- Acute Systemic
- Pyrogenicity
- Hemolysis (direct and indirect)
- Complement Activation (SC5b-9)
- Thrombogenicity

Animal study: No animal studies were performed.
Clinical: No clinical evaluations of this product have been conducted.

5. Conclusion

The results of the above testing supported the substantial equivalence of the Introducer Sheath Set to the predicate device.