April 23, 2026

Cardiocycle Medical(Suzhou) Co., Ltd.
Siyu Chen
Regulatory Affairs Engineer
Unit 401&501, Bldg. C15, Stage 5, Biobay
#21 Chaoqian Rd., Suzhou Industrial Park
Suzhou, Jiangsu, 215000
China

Re: K254248
Trade/Device Name: Introducer Sheath Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 27, 2026
Received: March 27, 2026

Dear Siyu Chen:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.04.23 15:11:22 -04'00'

For
Misti Malone
Assistant Director
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)*
K254248

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

I. SUBMITTER

Name:	Cardiocycle Medical(Suzhou) Co.,Ltd.
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Contact Person:	Siyu Chen
Date Prepared:	April 23, 2026

II. DEVICE

510(k) Number:	K254248
Device Tradename:	Introducer Sheath Set
Common Name:	Introducer Sheath Set
Product Code:	DYB
Regulation:	21 CFR 870.1340
Classification Panel:	Cardiovascular
Classification Name:	Catheter introducer
Regulatory Class:	Class II

III. PREDICATE DEVICE

Predicate Device:	Introducer Sheath set (K251838)
Manufacturer:	Cardiocycle Medical（Suzhou）Co., Ltd.
Reference Device:	Tearaway Introducer Sheath (K153533)
Manufacturer:	Galt Medical Corp.

IV. 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.

The sheath is offered in models with Minimum Internal Diameters 3.9–8.6 mm, Nominal Outer Diameters 4.8–9.5 mm, and Effective Lengths 150-650 mm. The dilator is offered in models with Minimum Internal Diameter 0.9 mm, Nominal Outer Diameters 4.1–8.7 mm, and Effective Lengths 250-795 mm.

V. INDICATIONS 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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE DEVICE

The intended use and indications for use for the Introducer Sheath device are identical to the predicate Introducer Sheath set (K251838). The subject and predicate device are identical in principles of operation, components, design, materials, structural composition, sterilization, and manufacturing process. The only difference is the addition of models with new shorter effective lengths of the sheath and dilator than the predicate device. A reference device was used to support the use of the shorter lengths and smaller diameters in the intended vasculature.

VII. PERFORMANCE DATA

Non-clinical performance testing, biocompatibility, sterilization, packaging, and shelf life were leveraged from the predicate device. The following additional non-clinical performance tests were performed to support the substantial equivalence determination.

- Visual Inspection/Appearance
- Dimensional Verification
- Tensile Strength

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

VIII. CONCLUSIONS

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