January 19, 2023

Merit Medical Systems, Inc.
Kirk Mcintosh
Senior Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K223872
Trade/Device Name: Low Profile Companion Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB, DRE
Dated: December 23, 2022
Received: December 23, 2022

Dear Kirk Mcintosh:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 2023.01.19 10:26:47 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223872

Device Name
Low Profile Companion Sheath

Indications for Use *(Describe)*
The Merit Low Profile Companion Sheath is indicated to be used for the introduction of interventional and diagnostic devices into the peripheral (and coronary) vasculature.

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.

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510(k) Summary

Prepared on: 2023-01-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Merit Medical Systems, Inc.
Applicant Address	1600 West Merit Parkway South Jordan UT 84095 United States
Applicant Contact Telephone	(801) 316-3695
Applicant Contact	Mr. Kirk McIntosh
Applicant Contact Email	kirk.mcintosh@merit.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Low Profile Companion Sheath
Common Name	Catheter introducer
Classification Name	Introducer, Catheter
Regulation Number	870.1340
Product Code	DYB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211405	Prelude® Guide Sheath	DYB

Device Description Summary

21 CFR 807.92(a)(4)

General Description:
The Low Profile Companion Sheath is a sterile, disposable device consisting of (a) a coil reinforced shaft with an atraumatic tip and the distal end; (b) a hemostasis valve with a side port and stopcock; and (c) a tapered tip dilator with snap-fit hub at the proximal end.

(a) Shaft. The coil reinforced, multi-layer polymer shaft contains a tapered tip at the distal end. A continuous inner PTFE tube forms the core of the shaft and provides a circular working lumen through which devices can be passed. A hydrophilic coating is applied to the entire outer surface of the shaft. A radiopaque marker made of platinum iridium is embedded 5mm from the distal end of the shaft. At the proximal end of the shaft, a female, winged luer hub is over-molded onto the shaft to support handling and to provide for the connection of the hemostasis valve.
(b) Hemostasis valve. A removable hemostasis valve is thread onto the luer hub at the proximal end of the shaft. Inside the valve housing, a lubricated, silicone slit disc provides a seal around devices passed through the sheath, thereby preventing blood leakage through the valve. Just distal of the valve, the valve housing is connected to a side port leading to a three-way stopcock valve. The sideport is used for flushing the introducer sheath.
(c) Dilator. The dilator made of a polypropylene blend contains a full-length round lumen to allow placement over a guidewire. The distal end of the dilator is configured as a tapered tip that extends about 2 cm beyond the end of the sheath when the dilator is fully inserted through the sheath.

The Low Profile Companion Sheath is a prescription medical device that is used only in healthcare facilities and hospitals. The device is placed in patients for up to 24 hours.

Principle of Operation:
The device is operated manually and is to be handled aseptically by qualified medical personnel familiar with its application.
After removal from the sterile pouch packaging using aseptic techniques, the device is placed into the vasculature. Prior to use, the

introducer sheath and dilator are flushed with heparinized solution. The dilator is then inserted completely into the introducer sheath and locked into place through the snap fit connection at the housing of the hemostasis valve. The dilator-sheath-combination is then passed as one unit over a guide wire with a maximum size of up to 0.038 inches. Once the introducer sheath is fully placed in the patient, the guide wire and dilator are removed and compatible catheters and instruments can be inserted through the introducer sheath.
For removal of the sheath, a guide wire is inserted past the distal tip of the sheath and the dilator is passed over the wire into the sheath. Sheath and dilator are then removed as one unit.

Device Models:
The lone configuration of the Low Profile Companion Sheath is a 7-French diameter, 30 cm in length and a straight shape.

Comparison of Technological Characteristics with the Predicate Devices:
The Low Profile Companion Sheath is manually operated, sterile, single use sheath system made predominantly of thermoplastic polymers. The sheath is reinforced with a stainless-steel coil which provides kink resistance when passed through tortuous paths. With regard to the design, device features, method of sterilization, and mode of operation, the Low Profile Companion Sheath does not differ from the predicate devices. Materials used to manufacture the Low Profile Companion Sheath are identical to those used in the legally marketed predicate device.
Other than the shorter length there are no differences in the technological characteristics between the subject device and the predicate device. The Low Profile Companion Sheath complies to the same standards as the predicate device.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Merit Low Profile Companion Sheath is indicated to be used for the introduction of interventional and diagnostic devices into the peripheral (and coronary) vasculature.

Indications for Use Comparison 21 CFR 807.92(a)(5)

There is no change in the Indications for Use statement from the predicate to the subject device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device is substantially equivalent to the predicate device based on an identical Indications for Use statement, the same basic performance and safety profile, principle of operation, fundamental design principles, and manufacturing technology.

The primary reason for submitting this Special 510(k) is to document an extension to the product line. The subject device is shorter in length than the shortest cleared configuration under K211405.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following design verification tests were performed to demonstrate that the Low Profile Guide Sheath met predetermined specifications and to assure that there were no unacceptable risks associated with the modifications:

- Hydrophilic Coated Length
- Sheath Tip to Dilator Taper Length
- Sheath Effective Length

The results of the testing demonstrated that the subject Low Profile Companion Sheath met the acceptance criteria applicable to the changed dimensions of the device.

Based on the indications for use, design, safety and performance testing, the subject Low Profile Companion Sheath raises no new questions of safety and effectiveness compared to the predicate device and is substantially equivalent to the predicate device manufactured by Merit Medical Systems, Inc.