July 27, 2026

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

Re: K261310
Trade/Device Name: FlexTract Deflectable-Rotational Dilator Sheath Set
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: June 26, 2026
Received: June 26, 2026

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 (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,

JESSICA L. BATISTA -S
Digitally signed by JESSICA L. BATISTA -S
Date: 2026.07.27 13:01:39 -04'00'

Jessica Batista Bertolini
Acting Assistant Director
DHT2A: Division of Cardiac Electrophysiology, Diagnostics, and Monitoring 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)*
K261310

Device Name
FlexTract Deflectable-Rotational Dilator Sheath Set

Indications for Use *(Describe)*
The FlexTract Sheath Set is indicated for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads.

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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FlexTract Deflectable-Rotational Dilator Sheath Set
510(k) Summary

General Provisions	Submitter Name: Merit Medical Systems, Inc. Address: 1600 West Merit Parkway South Jordan, UT 84095 Telephone Number: (801) 316-3695 Contact Person: Kirk McIntosh Date Prepared: April 15, 2026 Registration Number: 1721504
Subject Device	Trade Name: FlexTract Deflectable-Rotational Dilator Sheath Set Common/Usual Name: Dilator, Vessel, for Percutaneous Catheterization Classification Name: Dilator, Vessel, for Percutaneous Catheterization Regulatory Class: II Product Code: DRE 21 CFR §: 870.1310 Review Panel: Cardiovascular
Predicate Device	Trade Name: Evolution RL Controlled-Rotation Dilator Sheath Set Classification Name: Dilator, Vessel, for Percutaneous Catheterization Premarket Notification: K141148 (submitted by Cook Vascular Inc.) Manufacturer: Merit Medical Systems, Inc.* * In 2024, Merit Medical acquired K141148 portfolio of devices from Cook Medical This predicate has not been subject to a design-related recall.
Reference Device	No reference devices were used in this submission.
Device Description	The FlexTract Deflectable-Rotational Dilator Sheath Set is a handheld, manually operated, mechanically rotating and deflectable lead extraction tool for use during transvenous lead extraction (TLE) procedures. Its primary function is to dilate tissue and fibrous attachments which may be anchoring the targeted lead to the inner vascular wall, thereby facilitating removal of the lead. The FlexTract Sheath Set is comprised of a polymer/stainless steel braided sheath connected to a polymeric ergonomic handle/trigger capable of mechanically rotating a stainless-steel dilating tip at the distal terminus of the device. It is designed for the user to be able to rotate the distal tip in either a bi-directional or uni-directional manner. To facilitate passage through tortuous anatomy, the FlexTract is designed with manual controls to allow the user to deflect the distal section of the sheath and choose the direction of deflection. A radiopaque polytetrafluoroethylene (PTFE) Outer Sheath accessory is provided with the FlexTract device and may be used to provide manual dilation or as a stiffening aid of the FlexTract shaft during use. The FlexTract Sheath Set is available in 9 Fr, 11 Fr, 13 Fr and 16 Fr configurations with a working length of 46 cm. It is labeled for single-use and provided sterile (ethylene oxide).

Indications for Use	The FlexTract Sheath Set is indicated for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads. The indications of the subject device are only a subset of those of the predicate. The change does not represent an increase in the level of specificity of the indication for use. The difference in indications is not critical to the intended surgical use of the device.
Comparison to Predicate Device	The subject FlexTract Sheath Set is similar in design and technological characteristics to the predicate Evolution RL Sheath Set. The comparison between the subject device and predicate devices is based on the following: • The Indications for Use are a subset of those of the predicate • Same fundamental technology • Same sterilization methods • Same labeling The following technological differences exist between the subject device and predicate device: • Minor dimensional differences • Addition of a larger (16 Fr) configuration • Addition of design feature to allow deflection and positioning of the distal section of the device • Different patient contacting materials that meet ISO 10993-1 requirements • Packaging configuration includes a protective tray within the sealed pouch The design, material, dimensional, and packaging differences are considered technological differences but do not raise new or different questions of safety and effectiveness and can be evaluated with performance testing.
Performance Data	No specific FDA guidance documents or recognized performance standards have been established for the subject device classification. A battery of tests was performed based upon risk analysis and the requirements of the following internationally recognized standards and guidance documents pertaining to the device performance, as well as biocompatibility, sterilization, and labeling standards and guidance. Conformity to these standards demonstrates that the proposed FlexTract Sheath Set meets the acceptance criteria established by the standards. • FDA guidance document: Use of International Standard ISO 10993-1 (2023), “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process” • ISO 11607-1 (2023), Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems • ASTM D4169-22, Standard Practice for Performance Testing of Shipping Containers and Systems • ISO 2233 (2001), Packaging – Complete, Filled Transport Packages and Unit Loads – Conditioning for Testing • ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Performance Data (Continued)

- ASTM F1929-23, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F2096-19 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F88/F88M-23, Standard Test Method for Seal Strength of Flexible Barrier Materials
- ISO 10993-1 (2025), Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process
- ISO 10993-4 (2017), Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood
- ISO 10993-5 (2009), Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 (2021), Biological evaluation of medical devices – Part 10: Tests for irritation and delayed type hypersensitivity
- ISO 10993-11 (2017), Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- ISO 10993-12 (2025), Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- ISO 10993-23 (2025), Biological evaluation of medical devices - Part 23: Tests for irritation
- ASTM F756-17, Standard Practice for Assessment of Hemolytic Properties of Materials
- USP 43-NF38:2020, <151> Pyrogen Test (USP Rabbit Test)
- ANSI/AAMI HE75 (2018), Human factors engineering - Design of medical devices
- IEC 62366-1 (2020), Medical devices - Part 1: Application of usability engineering to medical devices

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the FlexTract Sheath Set was conducted in accordance with the FDA guidance document: Use of International Standard ISO-10993-1, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process” and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Hemolysis
- Thrombogenicity
- Complement Activation

The FlexTract Sheath Set meets the biocompatibility requirements for externally communicating devices with circulating blood contact for a limited (< 24 hours) duration.

Performance Data (Continued)	The results of the following performance tests demonstrated that the subject FlexTract Sheath Set met the acceptance criteria applicable to the device. <u>Performance / Design Verification Testing:</u> (including shelf-life stability and distribution testing) • Dimension verification • Visual inspection • Cyclical testing • Critical functions (Deflection, Tab rotation, Tip rotation, Trigger pull) • Bend without deformation • Tip rotation testing • 3-Point bend stiffness • Dial rotation • Maximum deflection • Tip to Tab Alignment • Coaxiality when relaxed • Trigger force testing • Sheath retraction while deflected • Dial torque • Tip to Handle force comparison • Device Torsional testing • Radiopacity • Visual Inspection – Packaging • Dye Penetration – Packaging • Underwater Bubble Emission Testing – Packaging • Tensile Strength – Packaging <u>Design Validation Testing:</u> • Clinician simulated use, bench-top testing with phantom model • Summative and HFE activities
Summary of Substantial Equivalence	Based on the indications for use, design, safety, and performance testing, the subject FlexTract Deflectable-Rotational Dilator Sheath Set meets the requirements that are considered essential for its intended use, does not raise new questions of safety or effectiveness, and is therefore substantially equivalent to the predicate device, the Evolution RL Controlled-Rotation Dilator Sheath Set (K141148).