July 13, 2026

Merit Medical Ireland , Ltd.
Siobhan King
Principal RA Specialist
Parkmore Business Park W.
Galway,
Ireland

Re: K261640
Trade/Device Name: Merit MAK Nitinol/Gold-Tungsten Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: May 18, 2026
Received: May 18, 2026

Dear Siobhan King:

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,

LYDIA S. GLAW -S

Digitally signed by LYDIA S. GLAW -S
Date: 2026.07.13 14:35:45 -04'00'

Lydia Glaw
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)*
K261640

Device Name
Merit MAK Nitinol/Gold-Tungsten Guide Wire

Indications for Use *(Describe)*
The Merit MAK is intended for percutaneous placement of a 0.035" (0.89mm) or 0.038" (0.97mm) guide wire into the vascular and non-vascular system. This device is not intended for use in the coronary vasculature or neurovasculature.

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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510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Registration Number: Correspondent Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (+353) 91 703700 (+353) 91 703772 Siobhan King 1721504 Merit Medical Ireland Ltd. Parkmore Business Park West Galway, Ireland (+353) 91 703700 (+353) 91 703772 Siobhan King 18 May 2026 9616662
Subject Device	Trade Name: Common/Usual Name: Classification Name:	Merit MAK Nitinol/Gold-Tungsten Guide Wire Guidewire Catheter Guide Wire
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Merit MAK (Mini Access Kit) Dilator, Vessel, for Percutaneous Catheterization K031691 Merit Medical Systems, Inc.
Classification	Class II 21 CFR 870.1330 Catheter guide wire FDA Product Code: DQX Review Panel: Division of Cardiovascular Devices	
Indications for Use	The Merit MAK is intended for percutaneous placement of a 0.035” (0.89mm) or 0.038” (0.97mm) guide wire into the vascular and non-vascular system. This device is not intended for use in the coronary vasculature or neurovasculature	

Device Description	The Merit MAK (Mini Access Kit) utilizes a small coaxial introducer with dilator and guide wire for placement of larger diameter guide wires into the vasculature system when a small needle stick is preferred. The Merit MAK consists of the following components. These components may be packaged in a single pouch or may be packaged separately. • One (1) 4F or 5F coaxial introducer/dilator pair or 4F or 5F coaxial introducer/ stiffened dilator pair • One (1) 21 gauge introducer needle or 21 gauge echo enhanced introducer needle • One (1) 0.018" (0.46mm) guide wire, length range 40-80cm. Configurations include: Stainless Steel Core with Stainless Steel Tip; Stainless Steel Core with Platinum Tip; Nitinol Core with Platinum Tip. The guidewires are uncoated and have a straight or formed tip. One new version of the guidewire will be offered: • MAK Nitinol Core with Gold-Tungsten Tip Guidewire
Comparison to Predicate	The technological characteristics of the subject Merit MAK Nitinol/Gold-Tungsten Guide Wire are substantially equivalent to the Predicate MAK Nitinol/Platinum-Tungsten Guide Wire (K031691). The difference between the subject Merit MAK Nitinol/Gold-Tungsten Guide Wire and the Predicate MAK Nitinol/Gold-Tungsten Guide Wire (K031691) relates to a modification to the guidewire materials only. The fundamental technology and principles of operation of the subject and the predicate are the same. The subject and the predicate devices have the same indications for use.
Safety & Performance Tests	No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject MAK Nitinol/Gold-Tungsten Guide Wire was conducted based on risk analysis. A battery of testing was conducted in accordance with protocols based on requirements outlined in guidance's and industry standards and these were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence. Where appropriate, the tests were based on the requirements of the following documents: • FDA Guidance - "Coronary, Peripheral, and Neurovascular Guidewires Performance Tests and Recommended Labelling" – October 2019 • ISO 11070:2014/Amd 1:2018 – Sterile Single-Use Intravascular Introducers, Dilators and Guidewires (Reference Standard) • ISO 10555-1:2023 Intravascular catheters – Sterile and single use catheters • ISO 10993-1:2018 Biological Evaluation of Medical Devices • FDA Guidance – "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" – September 2023 • ISO 11135:2014/Amd.1:2018 Sterilization of health care products-Ethylene oxide • ISO 2233:2000 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

The following is a list of all testing that was successfully completed:

Design Verification:

- Dimensional Verification/Size Designation
- Visual Inspection/Surface
- Simulated Use
- Tensile Strength/Tip Pull
- Torque Strength
- Corrosion Resistance
- Kink Resistance
- Tip Flexibility
- Radiopacity
- Fracture Test
- Flexing Test

Design Validation:

- Simulated Use
- Needle Compatibility
- J-Straightening

Biocompatibility testing per ISO 10993-1:2018

The subject MAK Nitinol/Gold-Tungsten Guide Wire met the acceptance criteria and has demonstrated the subject MAK Nitinol/Gold-Tungsten Guide Wire is substantially equivalent to the Predicate MAK Nitinol/Platinum-Tungsten Guide Wire, K031691.

Summary of Substantial Equivalence

Based on the Indications for Use, design, safety and performance testing, the subject MAK Nitinol/Gold-Tungsten Guide Wire meets the requirements that are considered essential for its intended use and is substantially equivalent to the currently marketed predicate MAK Nitinol/Platinum-Tungsten Guide Wire, K031691 manufactured by Merit Medical.