May 22, 2026

Merit Medical Ireland, Ltd.
Brian Coughlan
Principal Regulatory Affairs Specialist
Parkmore Business Park W.
Galway,
Ireland

Re: K254137
Trade/Device Name: InQwire Amplatz Super Stiff Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: April 22, 2026
Received: April 22, 2026

Dear Brian Coughlan:

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,

JENNY R. KATSNELSON -S

Digitally signed by JENNY R. KATSNELSON -S
Date: 2026.05.22 10:27:23 -04'00'

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K254137

Device Name
InQwire Amplatz Super Stiff Guidewire

Indications for Use *(Describe)*
Merit Medical guide wires are used to facilitate the placement of devices during diagnostic and interventional procedures.

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

General Provisions

Submitter Name:	Merit Medical Systems, Inc.
Address:	1600 West Merit Parkway South Jordan, UT 84095
Telephone Number:	(+353) 91 703700
Fax Number:	(+353) 91 680104
Contact Person:	Brian Coughlan
Registration Number:	1721504
Correspondent Name:	Merit Medical Ireland Ltd.
Address:	Parkmore Business Park Parkmore, Galway, Ireland
Telephone Number:	(+353) 91 703700
Fax Number:	(+353) 91 680104
Contact Person:	Brian Coughlan
Date of Preparation:	19th December 2025
Registration Number:	9616662

Subject Device

Trade Name:	InQwire® Amplatz Super Stiff Guidewire
Common/Usual Name:	Guide Wire
Class:	II
Product code:	DQX
Classification Name:	Wire, Guide, Catheter
Regulation Number:	21 CFR 870.1330
Regulation Medical Specialty	Cardiovascular

510(k) Summary

Predicate Device	Trade Name:	InQwire® Amplatz Super Stiff Guidewire
	Class:	II
	Product code:	DQX
	Classification Name:	Wire, Guide, Catheter
	Regulation Number:	21 CFR 870.1330
	Regulation Medical Specialty	Cardiovascular
	Premarket Notification:	K163575 & K170700
	Manufacturer:	Merit Medical Systems Inc.

Device Description	Merit's InQwire Amplatz Super Stiff Guide Wires are 0.035" and 0.038" diameter with lengths of 75cm, 145cm, 180cm, 220cm or 260cm. The distal tip of the guide wire can be either Straight or with a 3mm J. The guide wire consists of a stainless-steel flat wire coil with a stainless-steel ground core wire placed inside. The assembled guide wire is spray coated with PTFE. The core wire has different ground distal profiles providing different stiffness's to meet clinical needs. For all the wire parts, the core wire is welded to the coil at the distal and proximal end. There is also a spot weld approx. 22cm from the distal end of the guide wire. The distal end of the coil has an open pitch section over approx. 7cm to give the end of the wire greater flexibility. The wires are placed in spiral dispenser with flush port and introducer. The dispenser with wire is then placed in a poly/Tyvek pouch and packaged 5 pouches per carton with one IFU
Indications for Use	Merit Medical guide wires are used to facilitate the placement of devices during diagnostic and interventional procedures.

510(k) Summary

Comparison to Predicate	Technological characteristics of the subject Merit InQwire Amplatz Super Stiff Guide Wire are substantially equivalent to those of the predicate Merit InQwire Amplatz Super Stiff Guide Wire (K163575, K170700). An alternate PTFE coating known as “Discrete coating” has been qualified at Merit Medical Coatings B.V. (Venlo, Netherlands). In addition to employing an alternate coating facility, there are formulation differences between the coating solutions used in the predicate and subject devices. The alternate coating process and formulation will apply to the full range of InQwire Amplatz Super Stiff Guidewires. The stainless steel core wire and coil wire of the subject Merit InQwire Amplatz Super Stiff Guidewire remain unchanged from the predicate InQwire Amplatz Super Stiff Guidewire (K163575, K170700). Based on the information presented herein, the subject Merit InQwire Amplatz Super Stiff Guide Wire is substantially equivalent to the predicate Merit InQwire Amplatz Super Stiff Guide Wire [K163575, K170700].
Safety & Performance Tests	No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. Safety and Performance tests were performed on the subject Merit InQwire Amplatz Super Stiff Guide Wire 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 with the predicate device. 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 • FDA Guidance – “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile” – January 2016

510(k) Summary

- ISO 11070:2014/Amd 1:2018, Sterile Single-Use Intravascular Catheter Introducers.
- ISO 11135:2014/Amd 1: 2018 Sterilization of health care products-Ethylene oxide-: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems.
- ISO 10993-1:2018, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process.
- FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff – September 2020.
- ISO 10993-7:2008/AMD1:2019, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals. The following is a list of all testing that was successfully completed:

<u>Performance Non-Clinical Testing-Bench</u>

- Dimensional Verification/Size Designation
- Finished Wire Surface (Visual Inspection)
- Simulated Use
- Coating Integrity
- Particulate Evaluation
- Lubricity
- Flex Testing
- Cytotoxicity
- Guinea Pig Maximization Sensitization Test
- Intracutaneous Irritation Test
- Acute Systemic Toxicity
- USP Rabbit Pyrogen Study
- Hemolysis – Direct Contact and Extract Method
- In-vitro Blood Loop Assay
- Complement Activation Assay
- Partial Thromboplastin Time (PTT) Assay
- Heparanized Platelet and Leukocyte Count Assay

510(k) Summary	
	All test results were comparable to the predicate devices and the subject Merit InQwire® Amplatz Super Stiff Guide Wire, met the predeterminded acceptance criteria.This has demonstrated that the subject device is substantially equivalent to the predicate devices.
Summary of Substantial Equivalence	Based on the comparisons noted the subject Merit InQwire Amplatz Super Stiff Guide Wire meets the requirements that are considered essential for its intended use and is substantively equivalent to the Predicate Merit InQwire Amplatz Super Stiff Guide Wire (K163575, K170700).