January 31, 2026

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

Re: K253847
Trade/Device Name: Splashwire Hydrophilic Guide Wire (MSWSTD35150J3)
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: December 2, 2025
Received: December 2, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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: 2026.01.31 14:13:08 -05'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253847

Device Name
Splashwire Hydrophilic Guide Wire

Indications for Use *(Describe)*
The Splashwire Hydrophilic Guide Wire is intended to be used in the peripheral vascular system to facilitate the placement of devices during diagnostic and interventional procedures.
Contraindications: These guide wires are not intended for Percutaneous Transluminal Coronary Angioplasty use or for use in the 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
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	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:	02 December 2025
	Registration Number:	9616662

510(k) Summary

Trade Name:	Splashwire Hydrophilic Guide Wire
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

Subject Device

510(k) Summary

Predicate Device

Trade Name:	Splashwire Hydrophilic Guide Wire
Class:	II
Product code:	DQX
Classification Name:	Wire, Guide, Catheter
Regulation Number:	21 CFR 870.1330
Regulation Medical Specialty	Cardiovascular
Premarket Notification:	K251181
Manufacturer:	Merit Medical Systems Inc.

Device Description

The Splashwire Hydrophilic guide wire consists of a nitinol core wire with a ground tapered distal section. A polyurethane jacket which contains tungsten for radiopacity is applied over the core wire and a hydrophilic coating is applied over the polyurethane jacket. The surface of the jacket is uniform with both the distal and proximal ends fully coated. The wire is placed inside a multiple loop flush dispenser, also referred to as a hoop. The dispenser has a flush port which facilitates solution flushing through the hoop to hydrate the guide wire. The wire is placed so that the distal end of the wire comes out of the outer portion of the hoop. A J-straightener is placed on the other end of the hoop to introduce the wire into the catheter. The wire is sold sterile and is a single use device. The subject Splashwire Hydrophilic Guide Wire Line Extensions and the predicate Splashwire Hydrophilic Guide Wire share the device characteristics described above, with the subject guide wire incorporating the following additional modifications:

J-Tip Guide Wires:
The J Tip devices incorporate a distal tip formed into a J shape. These guide wires are provided with a 3.0 mm J Tip.

510(k) Summary

Indications for Use	The Splashwire Hydrophilic Guide Wire is intended to be used in the peripheral vascular system to facilitate the placement of devices during diagnostic and interventional procedures. Contraindications: These guide wires are not intended for Percutaneous Transluminal Coronary Angioplasty use or for use in the neurovasculature.
Comparison to Predicate	The technological characteristics of the subject Splashwire Hydrophilic Guide Wire Guide Wire are substantially equivalent to those of the predicate Splashwire Hydrophilic Guide Wire Guide Wire [K251181]. Both the subject and predicate Splashwire Hydrophilic guide wire consist of a nitinol core wire with a ground tapered distal section. A polyurethane jacket which contains tungsten for radiopacity is applied over the core wire and a hydrophilic coating is applied over the polyurethane jacket. The surface of the jacket is uniform with both the distal and proximal ends fully coated. The wire is placed inside a multiple loop flush dispenser, also referred to as a hoop. The dispenser has a flush port which facilitates solution flushing through the hoop to hydrate the guide wire. The wire is placed so that the distal end of the wire comes out of the outer portion of the hoop. A J-straightener is placed on the other end of the hoop to introduce the wire into the catheter. The wire is sold sterile and is a single use device. The subject Splashwire Hydrophilic Guide Wire Line Extension and the predicate Splashwire Hydrophilic Guide Wire share the device characteristics described above, with the subject guide wire incorporating the following additional modifications: J-Tip Guide Wires: The J Tip devices incorporate a distal tip formed into a J shape. This 510(k) introduces guide wires with a 3.0 mm J Tip. The fundamental technology and operating principles of the subject and the predicate are the same. The subject and 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. Testing was conducted on the subject Splashwire Hydrophilic Guide Wire in accordance with protocols based on requirements outlined in guidances and industry standards and these were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence.

510(k) Summary

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 – “Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings - Labeling Considerations” – October 2019
- FDA Guidance – “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile” – January 2016
- 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 2020
- ISO 10993-1:2018, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 10993-18:2020, Biological evaluation of medical devices – Part 18: Chemical characterization of materials
- TIR28:2016, Product adoption and process equivalence for ethylene oxide sterilization

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

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

- Dimensional Verification
- Finished Wire Surface
- Prolapse Test
- Torqueability
- Lateral Stiffness
- Catheter Compatibility
- Simulated Use Testing
- Kink Resistance
- Ancillary Device Compatibility

510(k) Summary

	All test results were comparable to the predicate Splashwire Hydrophilic Guide Wire and the subject Splashwire Hydrophilic Guide Wire met the predeterminded acceptance criteria. This demonstrated that the subject device is substantially equivalent to the predicate device.
Summary of Substantial Equivalence	Based on the comparisons noted, the subject Splashwire Hydrophilic Guide Wire meets the requirements that are considered essential for its intended use and is substantively equivalent to the Predicate Device, the Splashwire Hydrophilic Guide Wire [K251181].