March 20, 2026

FMD Co., Ltd.
Bynum Maximilian
International Business Director
2777 Yulupa Ave. Suite 303
Santa Rosa, California 95405-8584

Re: K260544
Trade/Device Name: FMD Peripheral Guide Wire F-14 Flex 6; FMD Peripheral Guide Wire F-14 Tapered 40; FMD Peripheral Guide Wire F-18 Flex SP; FMD Peripheral Guide Wire F-18 DP 25; FMD Peripheral Guide Wire F-18 Tapered 40
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: February 11, 2026
Received: February 18, 2026

Dear Bynum Maximilian:

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: 2026.03.20 11:16:12 -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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260544

Device Name
FMD Peripheral Guide Wire F-14 Flex 6;FMD Peripheral Guide Wire F-14 Tapered 40; FMD Peripheral Guide Wire F-18 Flex SP; FMD Peripheral Guide Wire F-18 DP 25; FMD Peripheral Guide Wire Tapered 40

Indications for Use *(Describe)*
FMD Peripheral Guidewires are intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral use only.

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
as required by 21 CFR 807.92

Date Prepared:	9 February 2026
Applicant:	FMD Co., Ltd. 1-57-7 Sasazuka, Shibuya-ku, Tokyo 151-0073 Japan Tel: +81-3-3320-0081, Fax: +81-3-3320-0082
Contact:	Mayumi Ito Regulatory & Quality Assurance Director FMD Co., Ltd. 1-57-7 Sasazuka, Shibuya-ku, Tokyo 151-0073 Japan Tel: +81-3-3320-0081, Fax: +81-3-3320-0082 e-mail: m-ito@fmd-j.com
Trade Name:	FMD Peripheral Guide Wire series • F-14 Flex 6 • F-14 Tapered 40 • F-18 Flex SP • F-18 DP 25 • F-18 Tapered 40
Device Classification:	Class 2 per 21 CFR §870.1330
Classification Name:	Catheter, Guide, Wire
Product Code:	DQX

INTENDED USE/INDICATIONS FOR USE:
The indications for use for the Subject device FMD Peripheral Guide Wire F-14 and F-18 cm are the same as those of the Predicate FMD Peripheral Guide Wire F-18 Flex and are as follows:

> FMD Peripheral Guidewires are intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral use only.

LEGALLY MARKETED PREDICATE DEVICE:

Predicate Device	
K212268	FMD Peripheral Guide Wire F-18 Flex
Reference Devices	
K212268	FMD Peripheral Guide Wire F-14 Flex

DEVICE DESCRIPTION:
The FMD Peripheral Guide Wire F-14 and F-18 are designed to facilitate the placement of interventional peripheral devices such as dilating balloon catheters, stent delivery systems and other peripheral artery diagnostic or therapeutic devices. The FMD Peripheral Guide Wire F-14 and F-18 in this submission are available in nominal diameters of 0.014 (F-14) and 0.018 (F-18) inches and nominal lengths from 190 cm to 300 cm. The FMD Peripheral Guide Wire F-14 and F-18 with a length of less than 300 cm are compatible exclusively with the FMD Guide Wire Extension, which can extend the guide wire length allowing for exchange of Over-The-Wire systems. The basic structure of the FMD Peripheral Guide Wire F-14 and F-18 consists of a stainless steel core wire and a stainless steel and platinum nickel coil assembly on the distal end of the device. The coil assembly is soldered to the core. The Pt-Ni radiopaque coil allows for visualization while using fluoroscopy. The proximal portion of the guide wire is coated with PTFE coating, and the distal portion is coated with a hydrophilic coating. The FMD Peripheral Guide Wire F-18 DP 25 is available with a pre-shaped tip configuration. All other models are available in straight tip configuration.

COMPARISON WITH PREDICATE DEVICES:

The Subject device FMD Peripheral Guide Wire F-14 and F-18 are substantially equivalent to the Predicate device FMD Peripheral Guide Wire F-18 Flex, cleared under **K212268**, based on the following:

- Same indications for use
- Same intended use
- Same fundamental materials and manufacturing process
- Same fundamental design and technology
- Same operating principles
- Same proven biocompatibility information
- Same materials and process for packaging
- Same sterilization method and process for devices

A comparison of the Subject device with the Predicate device is summarized in **Table 1** below.

Table 1: Comparison between Subject & Predicate Device Technological Characteristics:

Name of Devices		FMD Peripheral Guide Wire		
		F-18 Flex	F-14 Flex	F-14 Flex 6, F-14 Tapered40, F-18 Flex SP, Tapered 40, DP 25
		Predicate	Reference	Subject
510(k) status		K212268		TBD
Intended Use		Guide wire for percutaneous peripheral intervention		Same
Indications for Use		The FMD Peripheral Guide Wire is intended to facilitate the placement and exchange of diagnostic devices during intravascular procedures. This device is intended for peripheral use only.		Same
Nominal OD		0.018" (0.45 mm)	0.014" (0.36 mm)	Same
Overall Length		190-300 cm		Same
Coil		Pt-Ni		Same
Core Wire		SUS		Same
Distal Coating		Hydrophilic		Same
Sterilization		Ethylene Oxide		Same
Differences	Proximal Coating	PTFE		Same and Additional Color
	Tip Shape	Straight		Straight/Pre-shape

The technological modifications incorporated into the Subject Device include the addition of a preshaped distal tip model and the introduction of a new color. These modifications do not change the intended use or fundamental operating principles of the device.

NON-CLINICAL TESTING/PERFORMANCE DATA:
The following non-clinical bench testing was employed to evaluate the performance of the Subject device FMD Peripheral Guide Wire F-14 and F-18 after conducting a risk assessment in accordance with EN ISO 14971:2019 Medical devices-application of risk management to medical devices. The testing was performed in accordance with the FDA Guidance Document "Coronary, Peripheral and Neurovascular Guidewires – Performance Tests and Recommended Labelling" (2019).

- Dimensional Verification
- Visual Inspection
- Simulated Use
- Tensile Strength/Tip Pull
- Torque Strength
- Torqueability
- Coating Integrity
- Particulate Evaluation
- Lubricity
- Corrosion resistance
- Kink Resistance
- Tip Flexibility
- Radiopacity

The successful results of the testing demonstrated that the Subject device FMD Peripheral Guide Wire F-14 and F-18 met all acceptance criteria and performed similarly to the predicate device. Performance data demonstrate that the subject devices function as intended and have a similar performance profile to the predicate device.

BIOLOGICAL EVALUATION:
The following testing was performed to assess biocompatibility of the Subject device FMD Peripheral Guide Wire F-14 and F-18:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-mediated pyrogenicity
- SC Sc5b-9 pathway Complement Activation
- In Vivo Thrombogenicity
- Direct and Indirect Hemolysis

The results from testing listed above performed to assess the Predicate device FMD Peripheral Guide Wire F-18 Flex are also being leveraged for the Subject device. All the results support the biocompatibility of the Subject device FMD Peripheral Guide Wire F-14 and F-18.

STERILIZATION:
The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135:2014, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*, to provide a SAL of 10^{-6}. The Subject device FMD Peripheral Guide Wire F-14 and F-18 and the Predicate devices are similar with regards to all device and packaging characteristics that could affect the ability to sterilize the devices.

CLINICAL TESTING:
Clinical performance evaluations are not necessary to demonstrate substantial equivalence to the Predicate device.

CONCLUSION:
FMD Co., Ltd. has presented information in this premarket notification supporting the Subject device FMD Peripheral Guide Wire F-14 and F-18 as substantially equivalent with respect to technological characteristics and indications for use to the Predicate device.