June 13, 2024

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

Re: K240460
Trade/Device Name: FMD Peripheral Guide Wire F-18 Flex 400
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: May 14, 2024
Received: May 14, 2024

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 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.

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: 2024.06.13 15:34:45 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240460

Device Name
FMD Peripheral Guide Wire F-18 Flex 400

Indications for Use *(Describe)*
The FMD Peripheral Guide Wires are intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular 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:	27 September, 2023
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:	Takashi Higashikubo Regulatory & Quality Assurance Deputy 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: t-higashikubo@fmd-j.com
Trade Name:	FMD Peripheral Guide Wire series ・F-18 Flex 400
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-18 Flex 400 cm are the same as those of the Predicate FMD Peripheral Guide Wire F-18 Flex and are as follows:

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

LEGALLY MARKETED PREDICATE DEVICE:

Predicate Device	
K212268	FMD Peripheral Guide Wire F-18 Flex
Reference Devices	
K212268	FMD Guide Wire Extension F-14 EXT
K152740	TERUMO Radifocus Glidewire

Like the predicate, the Subject device FMD Peripheral Guide Wire F-18 Flex 400 is a sterile, single use guide wire that is inserted into the peripheral vascular system for intravascular procedures. It is intended for use only by physicians who are fully trained in angiography and percutaneous transluminal angioplasty (PTA). It is not a combination product, not electrically powered, and does not contain nanotechnology, animal or human derived materials.

DEVICE DESCRIPTION:

The basic design, materials, and manufacturing methods of the Subject device FMD Peripheral Guide Wire F-18 Flex 400 cm are identical to those of the 510(k) cleared models of the Predicate device FMD Peripheral Guide Wires and FMD Guide Wire Extension (K212268).

The Subject device FMD Peripheral Guide Wire F-18 Flex 400 cm is an 0.018-inch PJ (polymer jacketed) guidewire having nominal length of 400 cm, is designed to facilitate the use in combination with available interventional peripheral devices such as dilating balloon catheters, stent delivery systems and other peripheral artery diagnostic or therapeutic devices having longer over the wire catheter lengths.

In addition to the 190 cm, 235 cm, and 300 cm models that have already gained 510(k) clearance, the Subject device FMD Peripheral Guidewire F-18 Flex 400 cm model for the U.S., which is scheduled to be newly manufactured and sold, has an additional 100 cm of core wire that is not inserted into the patient body and has no patient contact, resulting in a total length of 400 cm.

COMPARISON WITH PREDICATE DEVICES:

The FMD Peripheral Guide Wire F-18 Flex 400 is 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 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	FMD Peripheral Guide Wire F-18 Flex 400 cm
		Predicate	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)	Same
Overall Length		190, 235 and 300 cm	400 cm
Coil		Pt-Ni	Same
Tapered Core Wire		SUS	Same
Tip Shape		Straight	Same
Polymer Cover		Yes	Same
Coating	Distal	Hydrophilic	Same
	Proximal	PTFE	Same
Sterilization		Ethylene Oxide	Same

The change in the length profile to the FMD Peripheral Guide Wire F-18 Flex for expanded compatibility with diagnostic and therapeutic devices during intravascular procedures does not change the indications for use of the Subject device FMD Peripheral Guide Wire F-18 Flex 400 cm and is not a change to the fundamental scientific technology.

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-18 Flex 400 cm 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). The successful results of the testing demonstrated that the changes in length and the permanent core-to-core adhesive bonding connection do not raise questions of safety and effectiveness, supporting the substantial equivalence to the predicate device.

- 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

BIOLOGICAL EVALUATION:

Consistent with FDA's 2020 guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process', the biocompatibility studies were not repeated. The Subject device FMD Peripheral Guide Wire F-18 Flex 400 cm has the same Material Formulation, same Manufacturing Process, similar Geometry (differing only in length), same Physical-Chemical Properties, same Body/Fluid Contact and same Sterilization Process/Method as those of the Predicate and Reference devices.

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-18 Flex 400 cm 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.

INSTRUCTIONS FOR USE:

One additional statement is added to the Instructions for Use of the Predicate FMD Peripheral Guide Wires cleared under K212268 to explicitly state that the length of wire inserted into the patient body should be less than 300 cm.

CONCLUSION:

FMD Co., Ltd. has presented information in this premarket notification supporting the Subject device FMD Peripheral Guide Wire F-18 Flex 400 cm as substantially equivalent with respect to technological characteristics and indications for use to the Predicate device.