May 27, 2022

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

Re: K212268
Trade/Device Name: FMD Peripheral Guide Wires F-14 and F-18, FMD Guide Wire Extension F-14 EXT
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: April 25, 2022
Received: April 26, 2022

Dear Maximilian Bynum:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212268

Device Name
FMD Peripheral Guide Wires F-14 and F-18
FMD Guide Wire Extension F-14 EXT

Indications for Use *(Describe)*
The indications for use of the FMD Peripheral Guide Wires F-14 and F-18 :
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.

The indications for use of the FMD Guide Wire Extension F-14 EXT :
The FMD Guide Wire Extension accessory is intended for extension of the working length of an already introduced guide wire when exchanging over-the-wire interventional devices during an angioplasty procedure.

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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Future Medical Design

510(k) Summary
as required by 21 CFR 807.92

Date Prepared:	16 July, 2021
Applicant:	FMD Co., Ltd. 1-57-7 Sasazuka, Shibuya-ku, Tokyo 151-0073 Japan Tel: +81-3-3320-0081, Fax: +81-3-3320-0082
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Trade Name:	FMD Peripheral Guide Wires F-14 and F-18 FMD Guide Wire Extension F-14 EXT
Device Classification:	Class 2 per 21 CFR §870.1330
Classification Name:	Catheter, Guide, Wire
Product Code:	DQX
Predicate Device:	ASAHI Peripheral Guide Wire ASAHI Gladius (K150445)
Reference Devices:	ASAHI Peripheral Guide Wire ASAHI Astato XS40 (K153443) ASAHI Peripheral Guide Wire ASAHI Treasure 12 (K061984) Boston Scientific V-18 Control Wire (K033742) Abbott Hi-Torque Winn 200T (K101648) Abbott DOC Guide Wire Extension (K931171)

INTENDED USE/INDICATIONS FOR USE:
The indications for use of the FMD Peripheral Guide Wire:
The FMD Peripheral Guide Wires F-14 and F-18 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.

The indications for use of the FMD Guide Wire Extension F-14 EXT:
The FMD Guide Wire Extension F-14 EXT accessory is intended for extension of the working length of an already introduced guide wire when exchanging over-the-wire interventional devices during an angioplasty procedure.

DEVICE DESCRIPTION:
The FMD Peripheral Guide Wires 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 guide wires are available in nominal diameters of 0.014 (F-14) and 0.018 (F-18) inches and nominal lengths from 190cm to 300cm. The F-14 and F-18 guide wires with a length of less than 300 cm are compatible exclusively with the FMD Guide Wire Extension F-14 EXT, which can extend the guide wire length allowing for exchange of Over-The-Wire systems. The guide wires are composed 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 is coated with PTFE. The distal section is coated with hydrophilic coating. All wires are available in a straight tip configuration.

The FMD Guide Wire Extension F-14 EXT is composed of a stainless steel core wire coated with PTFE. It has an outer diameter of 0.014" (0.36 mm) and a length of 165cm. Its distal end contains a connecting hypotube that is compatible with guide wires less than 300cm of both the F-14 and F-18 series.

Attachment of the FMD Guide Wire Extension F-14 EXT to FMD's extendable guide wire creates an extended guide wire that can be used to exchange out a percutaneous transluminal angioplasty (PTA) catheter without removing the original guide wire from the artery. When the exchange is complete, the FMD Guide Wire Extension F-14 EXT can be detached, and the original guide wire can be used in a conventional manner.

Future Medical Design

COMPARISON WITH PREDICATE DEVICES:

Comparisons of the FMD Peripheral Guide Wires F-14 and F-18 and predicate/ reference devices show that the technological characteristics of the subject device such as the components, design, materials, sterilization method, shelf life and operating principle are similar to the currently marketed predicate and reference devices. The intended use of the subject device and its predicates are the same.

Name of Devices		FMD Peripheral Guide Wires F-14 and F-18	ASAHI Gladius	ASAHI Astato XS40
		Subject	Predicate	Reference
510(k) status		TBD	K150445	K153443
Intended Use		Guide wire for percutaneous peripheral intervention		
Indications for Use		The FMD Peripheral Guide Wires F-14 and F-18 is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral use only.	This product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.	This product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.
Nominal OD		0.014" (0.36 mm) 0.018" (0.45 mm)	0.014" (0.36 mm) 0.018" (0.45 mm)	0.014" (0.36 mm)
Overall Length		190, 235 and 300cm	180 to 300cm	200 to 300cm
Coil		Pt-Ni and SUS	Pt-Ni and SUS	Pt-Ni
Tapered Core Wire		SUS	SUS	SUS
Tip Shape		Straight	Straight Pre-shaped	Straight
Polymer Cover		Yes No	Yes	No
Coating	Distal	Hydrophilic	Hydrophilic	Hydrophilic
	Proximal	PTFE	PTFE	PTFE
Sterilization		Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

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Name of Devices	FMD Guide Wire Extension F-14 EXT	DOC Guide Wire Extension
	Subject	Reference
510(k) status	TBD	K931171
Manufacturer	FMD	Abbott Vascular
Device Classification	Class 2 per 21 CFR §870.1330	
Classification Name	Catheter, Guide Wire	
Product Code	DQX-Catheter Guide Wire	
Intended Use/ Indications for Use	The FMD Guide Wire Extension F-14 EXT accessory is intended for extension of the working length of an already introduced guide wire when exchanging over-the-wire interventional devices during an angioplasty procedure.	The DOC Guide Wire Extension is intended to provide the necessary length to allow the exchange of one dilatation catheter for another while maintaining the position of the guide wire in the coronary artery. After the dilatation catheter exchange has been completed, the DOC Guide Wire Extension can be detached and the initial wire can be used as a conventional guide wire.
Nominal OD	0.014” (0.36 mm)	0.014” (0.36 mm)
Overall Length	165 cm	145 cm
Core	SUS	SUS
Coating	PTFE	PTFE
Sterilization	Ethylene Oxide	Ethylene Oxide

NON-CLINICAL TESTING/PERFORMANCE DATA:

Non-clinical laboratory testing was performed on FMD Peripheral Guide Wires F-14 and F-18 to determine substantial equivalence. The following testing/assessments were performed:

- 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 *in vitro* bench tests demonstrated that the FMD Peripheral Guide Wires F-14 and F-18 met all acceptance criteria and performed similarly to the predicate and reference devices.

BIOCOMPATIBILITY:

The following biocompatibility tests were completed:

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

CLINICAL TESTING

Clinical evaluation was not required for this device.

CONCLUSION:

The FMD Peripheral Guide Wires F-14 and F-18 have the same intended use and the same or similar technological characteristics such as components, design, materials, sterilization method, shelf life and operating principles as those of the predicate and reference devices.

Therefore, the FMD Peripheral Guide Wires F-14 and F-18 and FMD Guide Wire Extension F-14 EXT are substantially equivalent to the predicate devices.