March 3, 2021

Terumo Medical Corporation
Vaibhav Sivaramakrishan
Regulatory Affairs Specialist II
265 Davidson Ave., Suite 320
Somerset, New Jersey 08873

Re: K203521
Trade/Device Name: FineCross M3
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 30, 2020
Received: December 1, 2020

Dear Vaibhav Sivaramakrishan:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203521

Device Name
FineCross M3

Indications for Use *(Describe)*
The product (FineCross M3) is intended to be percutaneously introduced into blood vessels and support a guide wire while performing PCI (percutaneous coronary intervention). The product is also intended for injection of radiopaque contrast media for angiography. The product should not be used in cerebral and peripheral vessels.

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

A. SUBMITTER INFORMATION (807.92(a)(1))

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Date prepared: November 30, 2020

B. DEVICE NAME (807.92(a)(2))

Proprietary Name:	FineCross M3
Common Name:	Microcatheter
Classification Name:	Catheter, Percutaneous
Classification Panel:	Cardiovascular
Regulation:	21 CFR 870.1250
Product Code:	DQY
Classification:	Class II

C. PREDICATE DEVICE (807.92(a)(3))

The legally marketed device to which substantial equivalence is claimed is:

Predicate Device: K082519 – FINECROSS MG Coronary Micro-Guide catheter, manufactured by Ashitaka Factory of Terumo Corporation.

Reference Devices:

1. K152447: ASAHI Caravel, Asahi Intecc co., ltd.
2. K191560: Turnpike LP Catheter, Vascular Solution LLC.

D. REASON FOR 510(k) SUBMISSION

This traditional 510(k) for FineCross M3 is being submitted for the new device for the purposes of establishing substantial equivalence to a legally marketed predicate device.

E. DEVICE DESCRIPTION (807.92(a)(4))

Principle of Operation Technology

FineCross M3 submitted in this 510(k) and its predicate (K082519) are operated by a manual process.

Design/Construction

FineCross M3 is a single use, ethylene oxide sterilized device that is intended to be percutaneously introduced into blood vessels and support a guide wire while performing PCI (percutaneous coronary intervention). The product is also intended for injection of radiopaque contrast media for angiography.

FineCross M3 features a three-layer construction, which consists of a stainless steel mesh braid sandwiched between an outer layer of polyester elastomer and an inner layer of polytetrafluoroethylene. The outer surface of the catheter is coated with hydrophilic polymer.

Materials

The materials for FineCross M3 are provided in Table 5.1.

Table 5.1: List of Materials

No.	Raw material	Patient Contact
1*	Polyester elastomer Colorant	Direct
2	Stainless steel	Non-contact
3*	Polytetrafluoroethylene	Direct
4	Au (Gold)	Non-contact
5*	Dimethyl acrylamide-glycidyl methacrylate copolymer	Direct
6	Acrylic resin	Non-contact
7*	Polyamide	Indirect
8	Polyester elastomer Colorant	Non-contact

*Blood contacting material (External communicating Device, Circulating Blood, Limited Contact (<24 hours)

Specifications

The specifications for FineCross M3 are provided in Table 5.2.

Table 5.2: FineCross M3 Specifications

Part	Specifications
Catheter Size:	Distal 1.8 Fr. / Proximal 2.5Fr.
Catheter OD:	Distal OD 0.61mm Proximal OD 0.84mm
Catheter Effective Lengths*:	1300mm, 1500mm
Hydrophilic Coating Length:	750mm, 950mm
Maximum guidewire outer diameter:	0.014”

*The length from the proximal anti-kink protector to distal end of catheter shaft.

F. INDICATIONS FOR USE (807.92(a)(5))

The product (FineCross M3) is intended to be percutaneously introduced into blood vessels and support a guide wire while performing PCI (percutaneous coronary intervention). The product is also intended for injection of radiopaque contrast media for angiography. The product should not be used in cerebral and peripheral vessels.

The indications for use are equivalent to the predicate (K082519).

G. SUBSTANTIAL EQUIVALENCE COMPARISON (807.92(a)(6))

FineCross M3, the subject of this Traditional 510(k), is substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the predicate, K082519 – FINECROSS MG Coronary Micro-Guide catheter, manufactured by Ashitaka Factory of Terumo Corporation.

In addition to the above-listed primary predicate, Terumo has identified the following reference devices. These are market leading devices with the same intended use and basic design as the subject device. Since these devices are frequently used in clinical practice, Terumo felt it was appropriate to use them as references when setting the acceptance criteria for FineCross M3 performance testing.

1. Asahi Intecc co., ltd. ASAHI Caravel (K152447)
2. Vascular Solution LLC., Turnpike LP Catheter (K191560)

The comparison of the technological characteristics is summarized in Table 5.3.

Table 5.3: Summary of Comparative Information

Device Characteristic	Subject Device: FineCross M3	Predicate Device: FINECROSS MG Coronary Micro-Guide catheter (K082519)	Reference Device #1: ASAHI Caravel (K152447)	Reference Device #2: Turnpike LP Catheter (K191560)
Manufacturer	Ashitaka Factory of Terumo Corporation	Same	Asahi Intecc co., ltd.	Vascular Solution LLC.
Intended Use /Indications for Use	The product (FineCross M3) is intended to be percutaneously introduced into blood vessels and support a guide wire while performing PCI (percutaneous coronary intervention). The product is also intended for injection of radiopaque contrast media for angiography. The product should not be used in cerebral and peripheral vessels.	The product (Finecross™ MG) is intended to be percutaneously introduced into blood vessels and support a guide wire while performing PCI (percutaneous coronary intervention. The product is also intended for injection of radiopaque contrast media for angiography.	This microcatheter is intended to provide support to facilitate the placement of guide wires in the coronary and peripheral vasculatures, and can be used to exchange one guide wire for another. This microcatheter is also intended to assist in the delivery of contrast media into the coronary and peripheral vasculatures. Do not use this microcatheter other than for use in the coronary and peripheral vasculatures.	The Turnpike catheters are intended to be used to access discrete regions of the coronary and/or peripheral vasculature. They may be used to facilitate placement and exchange of guidewires and to subselectively infuse/deliver diagnostic and therapeutic agents.
Operation Principle	Manual	Same	Same	Same

Device Characteristic	Subject Device: FineCross M3	Predicate Device: FINECROSS MG Coronary Micro-Guide catheter (K082519)	Reference Device #1: ASAHI Caravel (K152447)	Reference Device #2: Turnpike LP Catheter (K191560)
Design/ Construction	Three layer construction catheter shaft with hydrophilic coating, distal tip and hub	Same	Multi layers construction catheter shaft with hydrophilic coating, distal tip and hub	Multi layers construction catheter shaft with hydrophilic coating, distal tip and hub
Materials	- Polyester elastomer w/ pigment* - Stainless steel - Polytetrafluoroethylene* - Au (Gold) - Dimethyl acrylamide-glycidyl methacrylate copolymer* - Polyamide* - Polyester elastomer w/ pigment - Acrylic resin * blood contacting material	- Polyester elastomer w/ pigment* - Stainless steel - Polytetrafluoroethylene* - Au (Gold) - Dimethyl acrylamide-glycidyl methacrylate copolymer* - Polyamide* - Polyamide elastomer w/ pigment - Acrylic resin *blood contacting material	Information not publicly available.	Information not publicly available.
Package	• Individual package on which the product label and the	Same	Same	Same

Device Characteristic	Subject Device: FineCross M3	Predicate Device: FINECROSS MG Coronary Micro-Guide catheter (K082519)	Reference Device #1: ASAHI Caravel (K152447)	Reference Device #2: Turnpike LP Catheter (K191560)
	peel-off labels are attached • 1 unit per package			
Specifications	• Effective lengths: 1300mm, 1500mm • Catheter size: Distal 1.8 Fr. / Proximal 2.5Fr. • Catheter OD: Distal:0.61mm Proximal:0.84mm • Maximum guidewire outer diameter: 0.014”	• Effective lengths: 1300mm, 1500mm • Catheter size: Distal 1.8 Fr. / Proximal 2.6Fr. • Catheter OD: Distal:0.60mm Proximal:0.87mm • Maximum guidewire outer diameter: 0.014”	• Effective lengths: 1350mm, 1500mm • Catheter size: Distal 1.9 Fr. / Proximal 2.6Fr. • Catheter OD: Distal:0.62mm Proximal:0.85mm • Maximum guidewire outer diameter: Unknown	• Effective lengths: 1350mm, 1500mm • Catheter size: Distal 2.2 Fr. / Proximal 2.9Fr. • Catheter OD: Distal:0.74mm Proximal:0.97mm • Maximum guidewire outer diameter: 0.014”
Sterilization	Ethylene oxide	Same	Same	Same
Shelf life	24 months	Same	unknown	unknown

H. NON CLINICAL TESTS (807.92(b)(1))

Performance Testing

Performance testing was conducted to ensure the substantial equivalence of FineCross M3 throughout the shelf life and to verify conformity to the applicable external and internal standards. With the exception of the Radio-detectability and Simulated Use Usability tests, the following performance tests were performed on non-aged and accelerated aged samples. Table 5.4 provides a list of performance tests that were performed on FineCross M3.

Table 5.4: Summary of Performance Testing

Test Item
Radio-detectability
Surface
Peak tensile force
Freedom from leakage
Flowrate
Distal tip
Fluid leakage
Sub-atmospheric pressure air leakage
Stress cracking
Resistance to separation from axial load
Resistance to separation from unscrewing
Resistance to overriding
Torque strength
Kink strength of catheter shaft
Compatibility with guide wire
Product dimension
Exterior sliding characteristics (early phase)
Particulate evaluation
Coating Integrity
Butting resistance
Strength of distal part
Simulated use Usability test

Performance testing met the predetermined acceptance criteria and is acceptable for clinical use throughout its shelf life.

Biocompatibility

In accordance with ISO 10993-1, FineCross M3 is classified as: Externally Communicating Device, Circulating Blood, Limited Contact (<24 hours). The finished device's patient contacting parts were tested in accordance with the tests recommended in the FDA *Guidance for Industry and Food and Drug Administration Staff - Use of International Standard ISO-10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."* Screening tests were performed on accelerated aged devices to show that the biocompatibility is maintained throughout the shelf life of the product. The table below provides a list of biocompatibility tests conducted on FineCross M3.

Table 5.5: Summary of ISO 10993 Biocompatibility Testing

Non-aged, sterile, whole device
Cytotoxicity
Sensitization
Intracutaneous Reactivity
Acute Systemic Toxicity
Pyrogenicity
Hemolysis
Thrombogenicity (with and without anticoagulant agent)
Complement Activation (C3a and SC5b-9)
Physicochemical Profile (Physicochemical and FT-IR)
Accelerated-aged (2 years), sterile, whole device
Cytotoxicity
Hemolysis
Physicochemical Profile (Physicochemical and FT-IR)

Results of the testing demonstrate that the device is biocompatible throughout the shelf life of the product.

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135:2018, *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 Sterility Assurance Level (SAL) of 10^{-6}.

I. CLINICAL TESTS (807.92(b)(2))

This 510(k) does not include data from clinical tests.

J. CONCLUSION (807.92(b)(3))

In summary, FineCross M3, subject of this 510(k), is substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the predicate, K082519 – FINECROSS MG Coronary Micro-Guide catheter, manufactured by Ashitaka Factory of Terumo Corporation.