July 22, 2021

Shanghai Kindly Medical Instruments Co., Ltd.
Xu Jianhai
RA Supervisor
No. 925, Jinyuan Yi Road
Shanghai, Shanghai 201803
China

Re: K201706
Trade/Device Name: KDL Micro catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 7, 2021
Received: June 22, 2021

Dear Xu Jianhai:

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)*
K201706

Device Name
KDL Micro catheter

Indications for Use *(Describe)*
KDL Micro catheter is used to provide support, to facilitate the placement of guidewires in the peripheral and coronary vasculature, and can be used to exchange one guidewire for another. It is also intended to assist in the delivery of diagnostics, embolic, or therapeutic materials into peripheral and coronary 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

This 510(k) Summary is being submitted in accordance with the requirements of the guidance The 510(k) Program and 21 CFR 807.92.

510(k) Number: K201706

1. Date of Submission: June 17, 2021

2. Applicant

Shanghai Kindly Medical Instruments Co., Ltd.
Address: 925 Jinyuan Yi Road, Shanghai, 201803, China
Contact: Jianhai Xu, Regulatory Affairs Supervisor
Tel.:+086-021-59140056
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3. Proposed Device

Trade Name: KDL Micro catheter
Review Panel: Cardiovascular
Regulation Number: 21 CFR 870.1250
Classification name: Percutaneous Catheter
Regulation Class: Class II
Product Code: DQY

4. Predicate device

a. 510(k) Number: K190401
Product Name: MAMBA and MAMBA Flex Microcatheters
Product Code: DQY
Device Class: II
Classification Name: Percutaneous Catheter
Regulation Number: 21 CFR 870.1250
Manufacturer: Boston Scientific Corporation.

b. 510(k) Number: K173548
Product name: Merit Pursue Microcatheter
Product Code: DQY
Device Class: II
Classification Name: Percutaneous Catheter
Regulation Number: 21 CFR 870.1250
Manufacturer: Merit Medical Systems, Inc

c. 510(k) Number: K082519

Product name: FINECROSS^{TM} MG Coronary Micro-Guide catheter
Product Code: KRA
Device Class: II
Classification Name: Catheter, Continuous Flush
Regulation Number: 21 CFR 870.1210
Manufacturer: TERUMO Corporation.

5. Device description

The KDL Micro catheter is available in two French configurations, 2.3F (proximal)/1.6F (distal) and 2.5F (proximal) /1.8F (distal), 110cm, 130cm, 150cm, 180cm of effective lengths.

The proposed device consists of Hub with luer connector, strain relief, catheter shaft, a radiopaque marker and soft tip. The catheter shaft and radiopaque marker consist of 3 layers, an outer layer of Eurelon or pebax tube containing $BaSO_4$, a middle layer of stainless steel braid mesh and an inner layer of PTFE tube, in addition, the middle layer of radiopaque marker consist of Platinoiridium, The radiopaque marker at the distal tip to facilitate fluoroscopic visualization. The soft tip consists of 2 layers, an outer layer of pebax tube containing BaSO4, an inner layer of PTFE tube. The outer surface of the micro catheter shaft is coated with a hydrophilic coating designed to facilitate the introduction of the micro catheter into the vasculature.

The distal tip of micro catheter is offered in straight (MCS) and swan neck (MCM) configurations.

All models of the catheter are designed to accept a maximum guidewire diameter of 0.010 inch or 0.014 inch.

6. Intended Use Statement

KDL Micro catheter is used to provide support, to facilitate the placement of guidewires in the peripheral and coronary vasculature, and can be used to exchange one guidewire for another. It is also intended to assist in the delivery of diagnostics, embolic, or therapeutic materials into peripheral and coronary vessels.

7. Substantially Equivalent comparison

Item	Proposed Device	Predicate Device			Comparison
		K190401	K173548	K082519	
Applicant	Shanghai Kindly Medical Instruments Co., Ltd	Boston Scientific Corporation.	Merit Medical Systems, Inc	Terumo Corporation	/
Product code	DQY	DQY	DQY	KRA	Same to K190401 and K173548
Device Classification	Class II,21 CFR 870.1250	Class II,21 CFR 870.1250	Class II,21 CFR 870.1250	Class II,21 CFR 870.1210	Same to K190401 and K173548
Indications for Use	KDL Micro catheter is used to provide support to facilitate the placement of guidewires in the peripheral and coronary vasculature, and be used to exchange one guidewire for another. Micro catheter also intended to assist in the delivery of diagnostics, embolic, or therapeutic materials into the peripheral and coronary vessels.	The MAMBA and MAMBA Flex microcatheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature, and be used to exchange one guidewire for another. The microcatheters are also intended to assist in the delivery of contrast media into the coronary vasculature.	The Microcatheter is intended for general intravascular use, including peripheral and coronary vasculature. Once the subselective region has been accessed, the Microcatheter can be used for the controlled and selective infusion of diagnostics, embolic, or therapeutic materials into vessels. The catheter should not be used in the cerebral 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 the purpose of angiography	Similar
Curve shape of the distal tip	Straight and swan neck configurations.	A variety of shapes.	Straight or pre-shaped 45 degree and swan neck configurations.	Straight or pre-shaped 70 degree	Similar
Effective Length	110cm,130cm,150cm, 180cm	135cm,150cm	110cm,130cm,150cm	130cm,150cm	Different

Device Configuration	Proximal luer hub, strain relief, catheter shaft, radiopaque marker, distal tip, hydrophilic coating.	Proximal luer hub, strain relief, catheter shaft (consist of coil), radiopaque marker, distal tip, hydrophilic coating.	Proximal winged hub, a tapered strain relief, catheter shaft, radiopaque marker, distal tip, hydrophilic coating.	Proximal hub, a tapered strain relief, catheter shaft, radiopaque marker, distal tip, hydrophilic coating.	Same
Material	Pebax ($BaSO_4$) or Eurelon (outer layer), stainless steel, PTFE (inner layer), TPU, PC, Platinoiridium, Hydrophilic coating.	Hydrophilic coating, catheter shaft consist of coil. Other materials are not known.	Nylon ribbon braiding, Platinum marker,Hydrophilic coating, Other materials are not known.	Pebax, Eurelon (outer layer), PTFE (inner layer), Nylon, Platinoiridium, Tungsten, Hydrophilic polymer.	Different
Principle of Operation	Manually tracked over a guidewire to access vasculature	Manually tracked over a guidewire to access vasculature	Manually tracked over a guidewire to access vasculature	Manually tracked over a guidewire to access vasculature	Same
Proximal and Distal OD	2.3F/1.6F ; 2.5F/1.8F	Not known, the inner lumen permits the use of 0.014 in or smaller guidewires	2.8F/1.7F ; 2.9F /2.0F	2.6F/1.8F	Different
Coating	Hydrophilic coating	Hydrophilic coating	Hydrophilic coating	Hydrophilic polymer	Same
Sterile package	Tyvek Pouch	Tyvek Pouch	Tyvek Pouch	Unknown	Same
Guidewire compatibility	≤0.014 in	≤ 0.014 in	≤ 0.018 in	≤ 0.014 in	Same as K190401 and K082519
Marker	A radiopaque marker	A radiopaque marker	A radiopaque marker	A radiopaque marker	Same
Method of supply	Sterile and single use	Sterile and single use	Sterile and single use	Sterile and single use	Same
Sterilization Method	EO	EO	EO	EO	Same
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}	10^{-6}	Same

8. The results of the comparison

The indication for use, design and materials used in KDL Micro Catheter are similar to the predicated device, MAMBA and MAMBA Flex Microcatheters, Merit Pursue Microcatheter and FINECROSS™ MG Coronary Micro-Guide catheter.

9. Performance data

Both bench and non-clinical testing was conducted on KDL Micro catheter to support a determination of substantial equivalence to the predicate devices.
The non-clinical, bench testing included:

1) Appearance
2) Length
3) Out diameter
4) Hub
5) Corrosion resistance
6) Liquid leakage
7) Air leakage
8) Bond strength
9) Burst pressure
10) Power injection flowrate
11) Flexibility and Kink Test
12) Torque resistance
13) Catheter insertion/retraction force
14) Particulate
15) Guidewire compatibility
16) Radio-detectability
17) EO residuals
18) ECH residuals
19) Sterility
20) Bacterial endotoxin

10. Biocompatibility Testing Summary

The following biocompatibility tests were conducted in compliance with ISO 10993-1 for externally communicating devices with limited exposure (<24 hours) to circulating blood.

Table 10-1 Biocompatibility tests

Items	Standards	Conclusion
In Vitro hemolytic	ASTM F756-17	Met the requirement
Acute System Toxicity	ISO 10993-11:2017	Met the requirement
In Vitro Cytotoxicity	ISO 10993-5:2009	Met the requirement
Skin Sensitization	ISO 10993-10:2010	Met the requirement
Intracutaneous reactivity	ISO 10993-10:2010	Met the requirement
Pyrogenicity	ISO 10993-11:2017	Met the requirement
In vivo thrombogenicity	ISO 10993-4:2017	Met the requirement
Complement activation	ISO 10993-4:2017	Met the requirement

The rests showed that subject device, KDL Micro catheter is biocompatible based on ISO 10993-1 standards.

11. Conclusion

Based on the indication for use, technological characteristics, and performance testing results，KDL Micro catheters are substantially equivalent to the predicate devices.