March 7, 2024

DK Medical Technology Co., Ltd.
% Heather Wang
Consultant
Microkn Medical Technology Service (Shanghai) Co., Ltd.
Room 901, No. 889, Pinglu Road, Jing'an District
Shanghai, 200435
China

Re: K232207
Trade/Device Name: D·Kutting™ PTA Scoring Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: PNO
Dated: January 30, 2024
Received: January 30, 2024

Dear Heather Wang:

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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2024.03.07 08:22:54 -05'00'

For

Gregory O'Connell
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)*
K232207

Device Name
D·Kutting™ PTA Scoring Balloon Dilatation Catheter

Indications for Use *(Describe)*
The D·Kutting™ PTA Scoring Balloon Dilatation catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.

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.

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510(k) Summary

According to the requirements Per 21 CFR §807.92, the following information is provided sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter:	
Name	DK Medical Technology Co., Ltd.
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Telephone	+86 512 69880808
Contact person	Shi Quan
Date of summary prepared	2024-02-27
Subject Device:	
Name	PTA Scoring Balloon Dilatation Catheter
Trade name	D·Kutting™ PTA Scoring Balloon Dilatation Catheter
Device classification name	Percutaneous Cutting/Scoring Catheter
510(k) number	K232207
Regulation number	21 CFR Part 870.1250
Product code	PNO
Classification	Class II
Predicate Device:	
Name	2cm Peripheral Cutting Balloon Microsurgical Dilatation Catheter
Device classification name	Percutaneous Cutting/Scoring Catheter
510(k) number	K151253
Regulation number	21 CFR Part 870.1250
Product code	PNO
Classification	Class II

1. Indications for use

The D·Kutting™ PTA Scoring Balloon Dilatation Catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.

2. Description of the Device

The D·Kutting™ PTA Scoring Balloon Dilatation Catheter is an Over-The-Wire (OTW) balloon catheter with a dual lumen shaft design. One lumen is used to pass the catheter over 0.018" or 0.035" guidewires. The second lumen communicates with the balloon and is used to inflate and deflate the balloon during the procedure. The guidewire lumen and the balloon lumen terminate at the proximal end of the catheter in a Y-connector manifold with Luer lock fillings. 3 scoring wires between the two marker bands are radially distributed every 120° and mounted on the surface of the balloon. A PVP coating is applied to the tip to enhance insertion and withdrawal performance. The D·Kutting™ PTA Scoring Balloon Dilatation Catheter will be available with balloon diameters 4.0 mm to 8.0 mm, balloon lengths 20 mm to 80 mm and with catheter lengths of 50 cm, 90 cm, and 130 cm. The diameter and length of the balloon and the diameter of the compatible guide wire are printed on the hub.

3. Comparison to Predicate Device

To verify the subject device equivalent with the predicate device, the Table 1 lists the comparison results of clinical characteristics, technical characteristics, biological characteristics.

Table 1 Descriptive Comparison

#	Characteristics	Subject Device	Predicate Device	Discussion
	Product Code	**PNO**	**PNO**	
	510(k) Number	**K232207**	**K151253**	
01	Intended use	The D·Kutting™ PTA Scoring Balloon Dilatation Catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.	The Peripheral Cutting Balloon catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.	SE
02	Indication for use	The D·Kutting™ PTA Scoring Balloon Dilatation Catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.	The Peripheral Cutting Balloon catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.	SE
03	Procedure	Percutaneous Transluminal Angioplasty (PTA)	Percutaneous Transluminal Angioplasty (PTA)	SE
04	Contraindications	Use of the D·Kutting™ PTA Scoring Balloon Dilatation Catheter is contraindicated in situations where the product would be passed through the struts of a previously placed stent	Use of the Cutting Balloon Device is contraindicated in situations where the Cutting Balloon Device would be passed through the struts of a previously placed stent as the	SE

#	Characteristics Product Code 510(k) Number	Subject Device PNO K232207	Predicate Device PNO K151253	Discussion
		as the deflated product could become entangled in the stent. The product is not for use in the coronary arteries and carotid arteries. The product is not intended for the expansion or delivery of stents.	deflated Cutting Balloon Device could become entangled in the stent. The Peripheral Cutting Balloon Device is not for use in the coronary arteries and carotid arteries. The Peripheral Cutting Balloon Device is not intended for the expansion or delivery of stents.	
05	Site of use	Hospitals and physician offices	Hospitals and physician offices	SE
06	Intended user	Physicians with adequate training in performance of percutaneous transluminal angioplasty	Physicians with adequate training in performance of percutaneous transluminal angioplasty	SE
07	Components	Integral exchange balloon dilatation catheters with components: tip, balloon, scoring wire, marker bands, inner lumen, strain relief, shaft tubing and hub.	Integral exchange balloon dilatation catheters with components: tip, balloon, blade, marker bands, inner lumen, strain relief, shaft tubing and hub.	SE
08	Catheter Type	OTW	OTW	SE
09	Materials	Proprietary Material Information	Proprietary Material Information	Difference 1
10	Guidewire Compatibility	0.018 inch/0.035 inch	0.018 inch	Difference 2
11	Sheath Compatibility	7F	7F	SE
12	Models	120models; Balloon diameter:4-8mm Balloon length:20-80mm Catheter Length:50-130cm	12models; Balloon diameter:5-8mm Balloon length:20mm Catheter Length:50-135cm	Difference 3
13	Nominal Pressure (atm)	8	6	Difference 4
14	RBP (atm)	20	10	Difference 4
15	Marker Bands Present	YES	YES	SE
16	Can Infuse Contrast	YES	YES	SE
17	Packaging Configuration	Pouch in Pressboard carton	Pouch in Pressboard carton	SE
18	Sterilization	EO sterilization, the SAL is 10-6	Irradiation sterilization	Difference 5

Difference 1:

The materials used are different. The biocompatibility testing and evaluation result of the subject device demonstrated that the subject device is biocompatible. The difference does not raise new questions of safety or effectiveness.

Difference 2:

The guidewire compatibility of the subject device consists of 0.018 inch and 0.035 inch models, while the guidewire compatibility of the predicate device consists of only 0.018 inch models. The subject device underwent performance testing for both guidewire sizes and demonstrated that the guidewire sizes were compatible with their labeled respective models. The difference does not raise new questions of safety or effectiveness.

Difference 3:

The minimum diameter of the subject device's balloon is 4 mm, and the maximum diameter is 8 mm. It is divided into 1 mm steps (4 mm, 5 mm, 6 mm, 7 mm, 8 mm). The minimum length of the subject device's balloon is 20 mm, and the maximum length is 80 mm. It is divided into 20 mm steps (20 mm, 40 mm, 60 mm, 80 mm). The minimum effective catheter length is 50 cm and the maximum is 130 cm. It consists of 50 cm, 90 cm, 130 cm.

The minimum diameter of the predicate device's balloon is 5 mm, and the maximum diameter is 8 mm. It is divided into 1 mm steps (5 mm, 6 mm, 7 mm, 8 mm). The length of the predicate device's balloon is only 20 mm. The minimum effective catheter length is 50 cm and the maximum is 135 cm. It consists of 50 cm, 90 cm and 135 cm.

The subject device underwent performance testing representative of the product size matrix and demonstrated acceptable performance. The difference does not raise new questions of safety or effectiveness.

Difference 4:

The Nominal Pressure and RBP of subject device is 8atm and 20atm respectively, and predicate device's is 6atm and 10atm respectively. The subject device underwent performance testing with regards to balloon performance, including Balloon diameter to inflation pressure, Balloon inflation time, Balloon deflation time and Balloon rated burst pressure and demonstrated acceptable performance. The difference does not raise new questions of safety or effectiveness.

Difference 5:

The subject device uses EO Sterilization, while the predicate device uses Irradiation sterilization. Both are established sterilization methods that target SAL 10^{-6}. The subject device underwent sterilization validation and sterility verification as part of shelf life testing, and demonstrated acceptable performance. The difference does not raise new questions of safety and effectiveness.

4. Performance data in support of the substantial equivalence

The following performance data were provided in support of the substantial equivalence.

4.1 Performance

In vitro performance tests are included: visual inspection, dimensional verification, crossing profile, hydration, simulated use, guidewire compatibility, sheath compatibility, air/liquid leak, Luer lock, flexibility and kink test, torque strength, particulate release, coating integrity, lubricity, balloon inflation time, balloon deflation time, RBP and compliance, balloon fatigue and free from leakage, catheter bond strength, tip pull test and radiopacity.

The test results met all acceptance criteria and verified that the design and construction are suitable for its intended use as recommended by the Class II Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submission (FDA; April 14, 2023).

4.2 Biocompatibility testing

Biocompatibility testing for the D·Kutting™ PTA Scoring Balloon Dilatation Catheter was performed in accordance with the recommendations of ISO 10993-1:2018 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process. Table 2 lists the testing. The results of the testing show that the subject device met all acceptance criteria and the subject device is biocompatible.

Table 2 Biocompatibility testing

Biocompatibility testing
Cytotoxicity
Irritation test
Sensitization test
Intracutaneous reactivity test
Systemic Toxicity test (Acute)
Pyrogen test
Hemocompatibility (Hemolysis, Complement activation, *in vivo* thrombo resistance, Platelet Leukocyte Testing and Partial Thromboplastin Time)

4.3 Sterility

The D·Kutting™ PTA Scoring Balloon Dilatation Catheter is sterile. The method employed for the sterilization of the D·Kutting™ PTA Scoring Balloon Dilatation Catheter is Ethylene oxide sterilization according to the EN 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.

4.4 Clinical Evidence

N/A

4.5 Animal Study

In vivo safety and performance of the subject device were studied in the animal model. Both the subject device and the predicate device were successfully deployed and it is demonstrated that the in vivo safety and operability of the subject device is not inferior to that of the predicate device.

4.6 Packaging/Shelf Life

Simulated shipping testing, accelerated aging testing, and sterility package validation were carried out to decide the shelf life of the subject device. Testing results demonstrated that the shelf life of the D·Kutting™ PTA Scoring Balloon Dilatation Catheter is 36 months.

5. Conclusion

Based on the verification and validation testing, the D·Kutting™ PTA Scoring Balloon Dilatation Catheter does not raise new questions of safety and effectiveness compared to the predicate device.

DK Medical Technology Co., Ltd.(DK) believes that the information and data provided clearly describes the D·Kutting™ PTA Scoring Balloon Dilatation Catheter and demonstrates that the device is substantially equivalent to the predicate device.