April 21, 2025

DK Medical Technology Co., Ltd.
Shi Quan
301 unit, bioBAY B1,
218 Xinghu Str. Suzhou Industrial Park,
Jiangsu, China
215123

Re: K242254
Trade/Device Name: D·Kutting ™ LL Peripheral Scoring Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: March 13, 2025
Received: March 13, 2025

Dear Shi Quan:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

GREGORY W. O'CONNELL -S

Digitally signed by GREGORY W. O'CONNELL -S
Date: 2025.04.21 10:28:29 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242254

Device Name

D·Kutting™ LL Peripheral Scoring Balloon Dilatation Catheter

Indications for Use *(Describe)*

The D·Kutting™ LL Peripheral Scoring Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in the coronary vasculature.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.
Address	301 unit, bioBAY B1, 218 Xinghu Str., Suzhou Industrial Park, Jiangsu, China, 215123
Telephone	+86 512 69880808
Contact person	Shi Quan
Date of summary prepared	2025-04-17
Subject Device:	
Name:	Peripheral Scoring Balloon Dilatation Catheter
Trade name:	D·Kutting™ LL Peripheral Scoring Balloon Dilatation Catheter
Device classification name:	catheter, percutaneous, cutting/scoring
Type of submission:	510(k) Traditional
510(k) number:	K242254
Regulation number:	21 CFR Part 870.1250
Product code:	PNO
Classification:	Class II
Manufacturer:	DK Medical Technology Co., Ltd.
Predicate Device:	
Name:	VASCUTRAK PTA DILATATION CATHETER (VASCUTRAK)
Device classification name:	catheter, percutaneous, cutting/scoring
510(k) number:	K103459
Regulation number:	21 CFR Part 870.1250
Product code:	PNO
Classification:	Class II
Manufacturer:	C. R. BARD, INC.
Reference Device:	
Name:	2cm Peripheral Cutting Balloon Microsurgical Dilatation Catheter

Device classification name:	catheter, percutaneous, cutting/scoring
510(k) number:	K151253
Regulation number:	21 CFR Part 870.1250
Product code:	PNO
Classification:	Class II
Manufacturer:	BOSTON SCIENTIFIC LIMITED

Device Description:

The Peripheral Scoring Balloon Dilatation Catheter is an over the wire (OTW) catheter. It features a non-compliant balloon with 3 scoring elements mounted longitudinally on its outer surface. The scoring element is attached on the surface of balloon by adhesive. The scoring elements were tightly circled by a nitinol wire and the cross section of the scoring element is a triangular. The length of the scoring element is according to effective length of balloon. The catheter has two radiopaque marker bands, which fluoroscopically indicates the expanded part of the balloon and aid in the placement of the balloon and scoring element and to facilitate proper placement. The two radiopaque marker bands are located on the inner-lumen which is underneath the balloon. The catheter includes a tapered tip to facilitate advancement of the catheter to and through the inflation site. A lubricious coating is applied at from the distal tip to shaft tubing to enhance insertion and withdrawal performance. The inner lumen in the shaft tubing and ends in a Y-connector manifold hub with 2 Luer lock fittings. The straight manifold port is used to pass the catheter over the suitable guidewire. The second side port communicates with the balloon and is used to inflate and deflate the balloon during the procedure. The diameter and length of the balloon and the diameter of the compatible guide wire are printed on the hub. The balloon is folded an inserted in a PTFE casing to protect the balloon and scoring element.

The Peripheral Scoring Balloon Dilatation Catheter is offered in balloon diameters ranging from 2.5mm-7.0mm and lengths are from 20mm to 150mm. The catheter length is 90cm, 135cm and 150cm and is compatible with 0.014″ or 0.018″ guide wires accordingly.

Indications for use:

The Peripheral Scoring Balloon Dilatation Catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in the coronary vasculature.

Comparative Analysis:

The subject device has equivalent indications for use as the predicate device, with the exception that there is no in-stent restenosis (ISR) indication for the subject device.

At a high level, the subject and predicate devices are based on the same technological elements. The subject device has equivalent technological characteristics (i.e., design, principle of operation) as the predicate device. While there is a difference in materials, dimension, RBP, the non-clinical testing results have demonstrated that the technological differences do not raise new questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary:

The following non-clinical testing was performed in accordance with the FDA Guidance Document titled Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters (April 14, 2023) to demonstrate that the subject device is substantially equivalent to the predicate device:

Bench testing

- Visual verification
- Dimensional verification (balloon, catheter, scoring element, crossing profile and others)
- Balloon compliance & RBP
- Coating integrity (Pre & Post)
- Simulated use
- Balloon inflation/deflation time
- Balloon fatigue
- Torque strength
- Flexibility and kink
- Catheter bond tensile strength
- Tip pull tensile
- Scoring performance
- Particulate evaluation
- Lubricity test

Biocompatibility testing

- Cytotoxicity
- Irritation test
- Sensitization test
- Intracutaneous reactivity test
- Systemic Toxicity test (Acute)
- Pyrogen test
- Hemocompatibility: (Hemolysis, Complement activation, in vivo thrombo resistance, and Partial Thromboplastin Time)

Animal Testing

- In vivo safety and performance of the subject device were studied in the animal model in acute (Day 0) and chronic (Day 30). Both the subject device and the control 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 control device.

Sterilization

- The product is sterile, SAL is 10^{-6}.
- Ethylene oxide sterilization is validated according to the EN ISO 11135:2014.

Packaging/Shelf-life

- Packaging validation
- Simulated shipping
- Accelerated aging
- Real time aging

Clinical Testing

- Not applicable

Conclusion:

The subject device, the Peripheral Scoring Balloon Dilatation Catheter, met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance and test protocols. Based on the verification and validation testing, the subject device does not raise new questions of safety and effectiveness compared to the predicate device.

The Peripheral Scoring Balloon Dilatation Catheter is substantially equivalent to the legally marketed predicate device.