April 5, 2023

DK Medical Technology Co., Ltd.
% Yuling Chen
Consultant
Microkn Business Consulting (Shanghai) Co., Ltd
Room 1219, Block A, No 3699, Gonghexin Road, Jingan District
Shanghai, 200435
China

Re: K214009
Trade/Device Name: D·Kaptain™ PTA High Pressure Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: February 26, 2023
Received: March 2, 2023

Dear Yuling Chen:

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,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.04.05 12:23:00 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214009

Device Name
D·Kaptain™ PTA High Pressure Balloon Dilatation Catheter

Indications for Use *(Describe)*
The D·Kaptain™ PTA High Pressure Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries and for 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.

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510(k) Number: K214009

510K 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.

Company:	DK Medical Technology CO., Ltd.(DK)
Address:	301 unit, bioBAY B1, 218 Xinghu Str., Suzhou Industrial Park
Proprietary Name	PTA High Pressure Balloon Dilatation Catheter
Trade Name	D·Kaptain™ PTA High Pressure Balloon Dilatation Catheter
Classification Name	Peripheral Transluminal Angioplasty Catheter
Regulation product codes	LIT, DQY
Classification	Class 11, 21 CFR Part 870.1250
Legal Manufacturer:	DK Medical Technology CO., Ltd.(DK)
Predicate Device	Mustang™ Balloon Dilatation Catheter
510(k) of the predicate device	K103751
Consultant	
Company	Microkn Business Consulting (Shanghai) Co., Ltd.
Address	Room 1219, Block A, No 3699, Gonghexin Road, Jingan District, Shanghai, China
Contact Person	Yuling Chen
Telephone	+86 15021397762
Email	yuling.chen@microkn.com

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission

1.Indications for use

The D·Kaptain™ PTA High Pressure Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

This catheter is not for use in the coronary vasculature.

2. Description of the Device

The D·Kaptain™ PTA High Pressure Balloon Dilatation Catheter is an over-the-wire balloon catheter with a dual lumen shaft design. One lumen is used to pass the catheter over 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. There are radiopaque marker bands located under the balloon to aid in positioning the system during the procedure. A PVP coating is applied to the tip to enhance insertion and withdrawal performance. The D·Kaptain™ PTA High Pressure Balloon Dilatation Catheter will be available with balloon diameters 3.0 mm to 12.0 mm, balloon lengths 20 mm to 150 mm and with shaft lengths of 50 cm, 75 cm, and 130 cm.

3. Comparison to Predicate Device

To verify the Proposed device equivalent with the predicate device, the tab.1 listed the comparison results of clinical characteristics, technical characteristics, biological characteristics.

Tab.1 Descriptive Comparison				
Serial Number	**ITEM**	**Proposed device**	**Predicate device**	**Discussion**
	Product Code	**LIT, DQY**	**LIT, DQY**	
	510(k) number	**K214009**	**K103751**	
01	Intended use	The D·Kaptain™ PTA High Pressure Balloon Dilatation Catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire for Percutaneous Transluminal Angioplasty in the peripheral vasculature and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.	The Mustang ™ Balloon Dilatation Catheter is intended for dilatation of Device stenosis in the peripheral vascular, for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae and post-deployed stent expansion of self-expanding and balloon expandable peripheral vascular stents.	SE
02	Indication for use	The D·Kaptain™ PTA High Pressure Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in the coronary	The Mustang™ Balloon Dilatation Catheter is indicated for percutaneous transluminal angioplasty (PTA) in the peripheral vasculature including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The MustangTM Balloon Dilatation Catheter is also indicated for post-dilatation of balloon expandable and self-expanding stents in the	SE

Tab.1 Descriptive Comparison				
Serial Number	**ITEM**	**Proposed device**	**Predicate device**	**Discussion**
	Product Code	**LIT, DQY**	**LIT, DQY**	
	510(k) number	**K214009**	**K103751**	
		vasculature.	peripheral vasculature. This catheter is not for use in coronary arteries.	
03	Location	Peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.	Peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.	SE
04	Procedure	Percutaneous Transluminal Angioplasty (PTA)	Percutaneous Transluminal Angioplasty (PTA)	SE
05	Contraindications	This catheter is not for use in the coronary. vasculature.	This catheter is not for use in coronary arteries.	SE
06	Site of use	Hospitals and physician offices	Hospitals and physician offices	SE

Tab.1 Descriptive Comparison				
Serial Number	**ITEM**	**Proposed device**	**Predicate device**	**Discussion**
	Product Code	**LIT, DQY**	**LIT, DQY**	
	510(k) number	**K214009**	**K103751**	
07	Intended user	Physicians with adequate training in performance of percutaneous transluminal angioplasty	Physicians with adequate training in performance of percutaneous transluminal angioplasty	SE
08	Components	Integral exchange balloon expandable catheters with components： tip, balloon, marker bands, inner lumen, strain relief, shaft tubing and hub.	Integral exchange balloon expandable catheters with components： tip, balloon, marker bands, inner lumen, strain relief, shaft tubing and hub.	SE
09	Catheter Type	OTW	OTW	SE
10	Materials	Nylon 12 , polyether block amide	Pebax7033, nylon 12	Difference 1
11	Device Coating(s)	No coating.	No coating.	SE
12	Models	189 models; balloon diameter: 3mm~12mm; balloon length: 20mm~150mm.	203 models; diameter: 3mm~12mm; balloon length: 20-200 mm.	Difference 2
13	Useable Catheter Length	75-130 cm	80-150 cm	SE
14	Guidewire Compatibility	0.035″	0.035″	SE
15	Nominal Pressure (atm)	8	8	SE
16	RBP (atm)	14-26	16-24	SE
17	Marker Bands	YES	YES	SE

Tab.1 Descriptive Comparison				
Serial Number	**ITEM**	**Proposed device**	**Predicate device**	**Discussion**
	Product Code	**LIT, DQY**	**LIT, DQY**	
	510(k) number	**K214009**	**K103751**	
	Present			
18	Can Infuse Contrast	YES	YES	SE
19	Packaging	Pouch in Pressboard carton	Pouch in Pressboard carton	SE
20	Sterilization	EO, the SAL is 10^{-6}	EO, the SAL is 10^{-6}	SE

Difference 1

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

Difference 2

The balloon length size of the subject device is less than the predicate device. The verification and validation testing of all sizes demonstrate the difference does not raise new questions of safety or 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, including visual inspection, dimensional verification, crossing profile, guidewire compatibility, simulated use, air/liquid leak, luer lock, flexibility and kink, torque strength, particulate release, coating integrity, lubricity, balloon rated burst pressure, balloon fatigue, balloon compliance, balloon inflation and deflation time, catheter bond strength, tip pull strength, trackability, and radiopacity were conducted. The test results met all acceptance criteria and ensure 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; January 13, 2020).

4.2 Biocompatibility testing

Biocompatibility testing for the D·Kaptain™ PTA High Pressure Balloon Dilatation Catheter was performed in accordance with the recommendations of ISO 10993-1, Biological Evaluation of Medical Device - Part 1: Evaluation and Testing. Tab.2 listing the testing results. The results of the testing show that the subject device included in this submission met all acceptance criteria and the subject device is biocompatible.

Tab.2 Biocompatibility testing
Cytotoxicity
Sensitization test
Intracutaneous reactivity test
Systemic Toxicity test (Acute)
Material-mediated pyrogenicity

Tab.2 Biocompatibility testing
hemocompatibility (hemolysis, complement activation, PTT, and in vivo thrombo resistance)

4.3 STERILITY

The D·Kaptain™ PTA High Pressure Balloon Dilatation Catheter is sterile. The method employed for the sterilization of the D·Kaptain™ PTA High Pressure 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

NA

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 D·Kaptain™ PTA High Pressure Balloon Dilatation Catheter.

Testing results demonstrated that the shelf life of the D·Kaptain™ PTA High Pressure Balloon Dilatation Catheter was 2 years.

5. Conclusion

Based on the verification and validation testing, the D·Kaptain™ PTA High Pressure 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·Kaptain™ PTA High Pressure Balloon Dilatation Catheter and demonstrates that the device is substantially equivalent to the predicate device.