May 14, 2021

Shanghai Kindly Medical Instruments Co., Ltd.
Jeffery Hui
Official Correspondent
No. 925, Jinyuan yi Road
Shanghai, Shanghai 201803
China

Re: K201929
Trade/Device Name: KDL Angiography Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: July 8, 2020
Received: July 10, 2020

Dear Jeffery Hui:

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 Interventional 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)*
K201929

Device Name
KDL Angiography Catheter

Indications for Use *(Describe)*
KDL Angiography Catheter are intended for delivery of radiopaque contrast media to selected sites during the angiography procedure of the peripheral and coronary vascular system.

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

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

510(k) Number: K201929

1. **Date of Submission:** May 13, 2021

2. **Applicant**

Shanghai Kindly Medical Instruments Co., Ltd.
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3. **Proposed Device**

Device Name: KDL Angiography Catheter
Review Panel: Cardiovascular
Regulation Number: 21 CFR 870.1200
Regulation name: Diagnostic intravascular catheter.
Regulation Class: Class II
Product Code: DQO

4. **Predicate Device**

	Device Name	510(k) No.	Product Code
Predicate Device	Radifocus® Optitorque™ Angiographic Catheter	K150232	DQO
Reference Device	Alvision™ Interventional Cardiology Diagnostic Catheter Alvicath™ Endovascular Diagnostic Catheter	K143604	DQO

5. **Device Description**

The proposed device consists of tube hub, strain relief, catheter shaft with stainless steel braid layer, soft extension and distal tip. The catheter shaft is made of Pebax contain Barium Sulfate that is radiopaque and a middle stainless steel braid layer. Soft extension and distal tip is made

of Pebax contain Barium Sulfate without stainless steel braid layer that could prevent vascular injury when pushed into the blood vessel.

The distal tip of the catheter is available in 32 kinds tip shape configurations. The outer diameter is available in 4F, 5F, 6F, 7F sizes and the length is available in 100cm except for Pig angiography catheter in length of 110cm. The side hole on distal tip is used to disperse the contrast media and balance pressure.

6. Intended Use Statement

KDL Angiography Catheter are intended for delivery of radiopaque contrast media to selected sites during the angiography procedure of the peripheral and coronary vascular system.

7. Substantially Equivalent comparison

Item	Proposed Device	Predicate Device	Reference Device	Note
	K201929	K150232	K143604	
Product code	DQO	DQO	DQO	Same
Indication for use	KDL Angiography Catheter are intended for delivery of radiopaque contrast media to selected sites in the angiography procedure of the peripheral and coronary vascular system.	The Radifocus Optitorque Angiographic Catheter is indicated for use in cardiac and vascular procedures. It is designed to deliver radiopaque media, guide wires, catheters, and therapeutic agents to selected sites in the vascular system. The different shapes are designed to selectively engage arteries from access sites such as the femoral, radial, and brachial artery.	Alvision™Interventional Cardiology Diagnostic Catheters are intended for use in the delivery of radio-opaque media to selected sites in the coronary vascular system. Alvicath™ Endovascular Diagnostic Catheters are intended for use in the delivery of radio-opaque media to selected sites in the peripheral vascular system.	Same
Principle of Operation	The proposed device is introduced into the blood vessel by the guide wire.	The predict device is introduced into the blood vessel by the guide wire.	The predict device is introduced into the blood vessel by the guide wire.	Same
Design Description	KDL Angiography Catheter consist of tube hub, strain relief, catheter shaft with stainless steel braid layer, catheter soft extension.	The Radifocus Optitorque Angiographic Catheter consist of catheter shaft, the soft tip, soft tube, tube hub and strain relief,.	Alvision™ and Alvicath™ are sterile, nonpyrogenic, single lumen catheters with a soft distal tip and a proximal strain relief and luer hub.	Same
Distal shape	32 distal shape configurations	A variety of distal shape configurations	A variety of distal shape configurations	Similar
Catheter size	4F, 5F, 6F, 7F	4F, 5F, 6F	4F, 5F, 6F, 7F	Same as K143604

Effective Length(cm)	100 cm,110 cm.	65cm, 80 cm, 90 cm, 100 cm, 110 cm.	45 cm, 60 cm, 65 cm, 80 cm,100 cm,110 cm	Similar
Side holes	Yes	Yes	Yes	Same
Sterile package	Yes	Yes	Yes	Same
Guidewire compatibility	Accept a maximum guidewire diameter of 0.038”	Accept a maximum guidewire diameter of 0.038”	Accept a maximum guidewire diameter of 0.038”	Same
Method of supply	Sterile and single use	Sterile and single use	Sterile and single use	Same
Material	Pebax, Barium Sulfate, stainless steel, Thermoplastic polyurethane (TPU), Polycarbonate (PC).	Pebax, Barium Sulfate, 316 stainless steel, Bismuth Oxide, Nylon, Barium Sulfate, Polyurethane elastomer, Polyamide elastomer, Polyamide, Polyethylene	Stainless steel wire, Nylon 12, Barium Sulfate, Pebax.	Different
Maximum Pressure	1200 psi	4 Fr: 750 psi 5 Fr and 6 Fr: 1000 psi	1200 psi	Same as K143604
Shelf life	Three years	Three years	Three years	Same
Sterilization Method	EO	EO	EO	Same
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}	Same

8. The results of the comparison

The indication for use, design and materials were used to determine equivalent performance in KDL angiography catheter, Radifocus Optitorque Angiographic Catheter and Alvision™, Alvicath™ Diagnostic Catheters.

9. Performance data

The following nonclinical bench testing was conducted on KDL angiography catheter to support to determine the performance proposed device is substantially equivalent to the predicate device.

1) Appearance
2) Length
3) Out diameter
4) Hub
5) Side holes
6) Corrosion resistance
7) Liquid leakage
8) Air leakage
9) Burst pressure
10) Dynamic flow rate and pressure
11) Bond strength
12) Tip pull test
13) Kink and flexibility test
14) Torque resistance
15) Catheter insertion/retraction force
16) Guidewire compatibility
17) Particulate
18) Radio-detectability
19) EO residuals
20) Sterility
21) Bacterial endotoxin

10. Biocompatibility Testing Summary

Biocompatibility testing was conducted in compliance with ISO 10993-1, for externally communicating devices with limited exposure (<24 hours) to circulating blood, and included the following tests:

Biocompatibility tests results

Items	Standard	Conclusion
In Vitro hemolytic	ASTM F756-17	The test result showed the test article had no influence on hemolytic properties
Acute System Toxicity	ISO 10993-5:2009	Under the conditions of this study, there was no evidence of systemic toxicity from the extract, the test article extract met the requirements of this study.
In Vitro Cytotoxiciy	ISO 10993-10:2010	Under the conditions of this study, the test article extract did not show potential toxicity to L-929 cells.
Skin Sensitization	ISO 10993-10:2010	No evidence of causing skin sensitization
Intracutaneous Reactivity	ISO 10993-11:2017	The test results showed that the polar and non-polar test article extracts did not induce intracutaneous reactivity in rabbit under the test condition
Pyrogenicity	ISO 10993-11:2006	No rabbit an individual rise in temperature of 0.5℃ or more
In vivo Thrombogenicity	ISO 10993-4:2017	Met the requirement of *in vivo* thrombogenicity test
Complement Activation	ISO 10993-4:2017	No influence on complement activity

In accordance with ISO 10993-1, the testing results demonstrated that KDL angiography catheter is biocompatible.

10. Conclusion

Based on the indication for use, technological characteristics and performance testing results, KDL angiography catheter is substantially equivalent to Radifocus Optitorque Angiographic Catheter and Alvision™, Alvicath™ Diagnostic Catheters.