September 10, 2018

Shanghai Kindly Medical Instruments Co., Ltd.
Su Jianhai
Regulatory Affairs Supervisor
No. 925, Jinyuan yi Road, 201803, Shanghai, China

Re: K180178
Trade/Device Name: KDL Introducer Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 4, 2018
Received: August 13, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Finn E. Donaldson -S

Digitally signed by Finn E. Donaldson -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000979673, cn=Finn E. Donaldson -S
Date: 2018.09.10 11:34:58 -04'00'

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K180178

Device Name
KDL Introducer set

Indications for Use *(Describe)*
Femoral artery Introducer Set: The Introducer set are intended to provide access and facilitate the introduction of guide wires, catheters and other accessory medical devices through the skin into the femoral artery while minimizing blood loss during interventional procedures.

Radial Artery Introducer Set: The Introducer set are intended to provide access and facilitate the introduction of guide wires, catheters and other accessory medical devices through the skin into the radial artery while minimizing blood loss during interventional procedures.

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

510(k) Number: K180178

1. Date Prepared: August 31, 2018

2. Submitter

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

Trade Name: KDL Introducer Set
Review Panel: Cardiovascular
Regulation Number: 21 CFR
870.1340 Regulation name: Catheter
introducer Regulation Class: Class II
Product Code: DYB.

4. Predicate device

510(k) Number: K140768
Product Name: Brilliant™ Introducer Kit
Manufacturer: Lepu Medical Tchnology (Beijing) Co., Ltd.

5. Device description

This set classifies two types: Femoral Artery and Radial Artery. The Femoral Artery introducer set consist of a sheath introdcuer, dilator, needle, Guidewire. The Radial Artery introducer set consist of a sheath introdcuer lubricated with/without hydrophilic coating, dilator, I.V. cannula /Introducer needle,Guidewire (with/without hydrophilic coating).
The Introducer Set consists of sheath introducer, each packaged in a set to together with a dilator, introdcuer needle, and guidewire. The introducer sheath is fitted with a hemostasis valve to

minimize blood loss during catheter introduction and/or exchange. A side port with tubing connected to a 3-way stopcocks is used for injection and injection contrast medium. The dilator is provided to aid in the introduction of sheath to the target vessel. The Introducer needle/I.V. Cannula is provided a conduit for insertion of the guidewire into the vascular system. The guidewire is utilized as a guiding mechanism for the insertion of the introducer sheath into the vascular system.

6. Indications for Use Statement:

Femoral artery Introducer Set: The Introducer set are intended to provide access and facilitate the introduction of guide wires, catheters and other accessory medical devices through the skin into the femoral artery while minimizing blood loss during interventional procedures.

Radial Artery Introducer Set: The Introducer set are intended to provide access and facilitate the introduction of guide wires, catheters and other accessory medical devices through the skin into the radial artery while minimizing blood loss during interventional procedures.

7. Non-clinical Test Conclusion

Testing were conducted to ensure the performance of the proposed device throughout the labeled shelf life, verify conformity to the applicable parts of standards and demonstrate substantial equivalence to the predicate device. The performance tests were performed on the non-aged and ages to 3 years sample. All sample tested met the standard applicable to each test.

The performance tests have completed per the following ISO standards:

Component	Testing item	Reference Standard/Guidance
Sheath introducer	Appearance	Section 4.3 of ISO 11070:2014
	O.D and I.D.	Section 7.2 a) of ISO 11070:2014
	Effective Length	Section 7.2 b) of ISO 11070:2014 (detail size see section Ⅴ in this submission)
	Luer connector	ISO 594-2
	Sheath introducer leakage	Section 7.3 of ISO 11070:2014
	Haemostasis valve leakage	Section 7.4 of ISO 11070
	Peak tensile force	Section 7.6 of ISO 11070
	Coating Integrity	In-house standard
	Coating Friction force	In-house standard
	Radio-dectectability	ASTM F640-12
Dilator	Appearance	Section 4.3 of ISO 11070:2014
	O.D. and I.D.	Section 9.2 a), b) of ISO 11070:2014

	Effective Length	Section 9.2 c) of ISO 11070:2014
	Luer connector	ISO 594-2
	Strength of union	Section 9.3.3 of ISO 11070:2014
	Coating Friction force	In-house standard
	Coating Integrity	In-house standard
	Radio-dectectability	ASTM F640-12
Introducer needle	Appearance	Section 4.3 of ISO 11070:2014
	O.D and I.D.	Table 1 of ISO 9626
	Effective Length	Section 5.2 of ISO 11070:2014
	Luer connector	ISO 594-1:1986
	Strength union	Section 5.4.2 of ISO 11070:2014
	Corrosion resistance	Section 4.4 ISO 11070:2014
	Needle point	Section 5.3 of ISO 11070
	Patency	Section 13.2 ISO 7864
	Stiffness	Section 5.8 of ISO 9626
	Breakage resistance	Section 5.9 of ISO 9626
	Limits for acidity and alkalinity	Section 5.4 of ISO 9626
Guidewire	Appearance	Section 4.3 of ISO 11070:2014
	O.D.	Section 8.2 a) of ISO 11070:2014
	Length	Section 8.2 b) of ISO 11070:2014
	Corrosion resistance	Section 4.4 ISO 11070:2014
	Fracture test	Section 8.4 of ISO 11070:2014
	Flexing test	Section 8.5 of ISO 11070:2014
	Peak tensile force	Section 8.6 of ISO 11070:2014
	Toque strength	3b of FDA Guidance for Coronary and Cerebrovascular Guidewire Guidance 1995
	Torqueability	3c of FDA Guidance for Coronary and Cerebrovascular Guidewire Guidance 1995
	Tip flexibility	3d of FDA Guidance for Coronary and Cerebrovascular Guidewire Guidance 1995
	Coating Integrity	In-house standard
	Coating Friction force	In-house standard
	Radio-dectectability	ASTM F640-12

The biocompatibility tests have completed as follows

Test Item	Reference Standards
In Vitro Hemolytic	ASTM F756-13 Standard Practice for assessments of hemolytic properties of material
In Vitro Cytotoxicity	ISO 10993-5:2009, Biocompatibility Evaluation of Medical Device - Part 5: Tests for In Vitro Cytotoxicity
Intracutaneous Reactivity	ISO 10993-10:2010, Biocompatibility Evaluation of Medical Device - Part 10: Tests for Irritation and Shin Sensitization
Skin Sensitization	ISO 10993-10:2010, Biocompatibility Evaluation of Medical Device - Part 10: Tests for Irritation and Shin Sensitization
Acute Systemic Toxicity	ISO 10993-11:2006, Biocompatibility Evaluation of Medical Device - Part 11: Tests for systemic toxicity
Pyrogen	ISO 10993-11:2006, Biocompatibility Evaluation of Medical Device - Part 11: Tests for systemic toxicity
In Vivo Thrombogenicity	ISO 10993-4:2002/Amd1:2006, Biocompatibility Evaluation of Medical Device - Part 4: Selection of tests for interactions with blood

8. Clinical Test

It is not applicable.

9. Summary Comparing the Technological Characteristics

The subject device has the same intended use, principle of operation, design and technological characteristics as the predicate device. Size, material of components, sheath hub, side port tubing, 3-Way Stopcock Body and cap, dilator tube, dilator hub and Guidewire J-Straightener are different from the predicate device. The finished product has been evaluated the biocompatibility testing and tested on safety and performance testing, and the result were complied with the test requirements and standards. Any the difference of subject device and predicate device did not raise any issues.

Table 3-1 Technological Characteristics Comparison List

Item	Proposed Device	Predicate Device (K140768)	Remark
Product Name	Introducer set	Brilliant^{TM} Introducer Kit	/
Product Code	DYB	DYB	Identical
Regulation No.	21 CFR 870.1340	21 CFR 870.1340	Identical
Classification	Class Ⅱ	Class Ⅱ	Identical

Intended Use	The Introducer set are intended to provide access and facilitate the introduction of guide wire, catheters and other accessory medical devices through the skin into femoral and/or radial artery and minimize blood loss during interventional procedures.	The Brilliant^{TM} Introducer Kit are intended for use to facilitate the introduction of guide wires, catheters and other accessory medical devices through the skin into a vein or artery and minimize blood loss associated with such introduction.	Identical
Principle of Operation	By manually operated	By manually operated	Identical
Components	A Sheath Introducer, a dilator, a Needle, a I.V. Needle,a Guidewire with straightener.	A sheath introducer, a dilator, a guide wire with a guide wire collimator, a puncture needle;an intravascular catheter with introducer needle, a scalpel and a syringe	Identical
Anatomical Locations	Femoral artery and Radial artery	Peripheral Vasculature	Identical
Hydrophilic coating	Only for Radial Sheath and Guidewire within type radial artery.	Sheath, dilator, guidewire	Analysis 2
Sheath hemostasis control	Hemostasis seal	Hemostasis seal	Identical
Product Specification			
Sheath length	110mm, 160mm	70mm~240mm	Analysis 3
Sheath French Size	5F~8F	4F~7F	Analysis 4
Guidewire Diameter	0.038", 0.021",0.025"	0.018"~0.035"	Analysis 5
Guidewire length	45cm	45cm and 70cm	Analysis 6
Needle	18G, 21G, 20G	20G and 22G	Analysis 7
Dilator	168mm, 218mm	125mm~295mm	Analysis 8
Package Content	Sheath Introducer, Dilator, Guidewire, Needle or I.V.Cannula	Sheath Introducer, a dilator, a giudewire, a puncture needle, intravascular catheter with introducer needle, a	Identical

		scalpel, a syringe.	
Material			
Outer Sheath	Fluorinated Ethylene Propylene (FEP)	Fluorinated Ethylene Propylene	Identical
Sheath Hub	Copolyester	Acrylobutyistyrene	Analysis 9
Side Port Tubing	Polyvinylchloride(PVC) Polyurethane (PU)	Ploy urethane	Analysis 10
Hemostasis Valve	Silicon	Silicon	Identical
3-Way Stopcock Body	Polyethyene (PE)	Acrylobutyistyrene	Analysis 11
Cap	Polycarbonate (PC)	Polyethyene	Analysis 12
Valve	Polyethyene (PE)	Polyethyene	Identical
Dilator Tube	Polypropylene (PP)	Polycarbonate	Analysis 13
Dilator Hub	Acrylobutyistyrene (ABS)	Acrylobutyistyrene	Analysis 14
Guidewire	Stainless Steel, Nickel Titanium Alloy, Thermoplastic Polyurethanes (TPU)	Stainless Steel, Stainless Steel w/nitinol core, or Polyurethane jacket w/nitinol coil	Identical
Guidewire J-Straightener	(High Density Polyethylene) HDPE	Polycarbonate	Analysis 15
Needle hub	Acrylobutyistyrene (ABS)/PC	Polycarbonate	Identical
Needle Tube	Stainless Steel	Stainless Steel	Identical
Protect Cover	PP/PE	Unknown	/
Sterilization Method	EO	EO	Identical
Sterility Level	SAL 10^{-6}	SAL 10^{-6}	Identical

10. Conclusion

Based on the result of the performance and biocompatibility testing, the proposed device, Introducer Set, met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, and test protocols. Therefore, the subject device is substantially equivalent to the legally market predicated device (K140768) in terms of intended use, principle of operation, design and technological characteristics.