September 13, 2022

Shanghai Kindly Medical Instruments Co., Ltd
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K222647
Trade/Device Name: INT Introducer Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: August 31, 2022
Received: September 1, 2022

Dear Prithul Bom:

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,

For

Misti Malone
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)*
K222647

Device Name
INT 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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

510(k) Number: K222647

1. **Date of Submission:** Aug, 25, 2022

2. **Submitter**

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

Trade Name: INT Introducer set
Common Name: Introducer set
Review Panel: Cardiovascular
Regulation Number: 21 CFR 870.1340
Classification name: INTRODUCER, CATHETER
Regulation Class: Class II
Product Code: DYB

4. **Predicate device**

510(k) Number: K180178
Trade Name: KDL Introducer Set
Product Code: DYB
Device Class: II
Classification Name: INTRODUCER, CATHETER
Regulation Number: 21 CFR 870.1340
Manufacturer: Shanghai Kindly Medical Instruments Co., Ltd.

5. **Device description**

The Introducer Set is supplied with an introducer sheath, a dilator, a guidewire and an access needle. These devices will be manufactured in 5.0, 6.0, 7.0, and 8.0 French and in lengths of 5, 7 and 11 centimeters. The sets are compatible with the supplied 0.018", 0.021'' guidewire and 21G needle in length of 7cm. The sets are supplied sterile and intended for single use.
The sheath shaft and hub are manufactured of Fluorinated ethylene propylene and copolyester; one-piece construction of the sheath shaft and hub allows smooth passage of medical devices. The hub, color-coded by French size, contains a hemostatic valve to prevent blood leakage during a procedure. A side tube equipped with a three-way stopcock is attached to the sheath hub. The side tube extension may be used for fluid and medication administration, as well as blood sampling.
The dilator is an open, tapered plastic tube with an integral luer hub for guidewire insertion.
The guidewire is inserted into the introducer sheath to facilitate and support entry of the sheath into the patient's vasculature. The dilator is longer than the sheath with a rounded tapered distal tip. The dilator tubes are manufactured of polypropylene. Dilator tubes are press-fit into the dilator hub with a bushing. The sheath hub and dilator hub lock using a rotating motion.

Introducer Set is designed specifically to introduce therapeutic or diagnostic devices into the vasculature. Using the Seldinger technique, the physician gains percutaneous access to the vascular system and then employs the introducer sheath as a conduit for inserting diagnostic and/or interventional devices into the patient.

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. Substantial Equivalence comparison

Item	Proposed Device	Predicate Device (K180178)	Remark
Trade Name	INT Introducer set	KDL Introducer set	/
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 INT Introducer set is intended to provide access and facilitate the introduction of guide wire and catheters through the skin into femoral or radial artery while minimize blood loss during interventional procedures.	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 while minimize blood loss during interventional procedures.	Similar, The intended use of predicate device cover that of proposed device.
Principle of Operation	By manually operated	By manually operated	Identical
Anatomical location	Femoral artery and Radial artery	Femoral artery and Radial artery	Identical
Intended patient population	Adult	Adult	Identical
Hydrophilic coating	No Hydrophilic coating	Only for Radial Sheath and Guidewire within type radial artery.	Analysis 1
Radio-opaque materials	Barium sulfate	Barium sulfate	Identical
Function of the side tube with three ways stop cock	Injection of saline and heparin	Injection and injection contrast medium	Analysis 2
Components	A Sheath Introducer, a dilator, a introducer Needle, a Guidewire.	A Sheath Introducer, a dilator, a Needle, a I.V. Needle, a Guidewire with straightener.	Similar, Analysis 8

Sheath hemostasis control	Hemostasis seal	Hemostasis seal	Identical
Product specification			
Sheath length	50mm, 70mm, 110mm	110mm, 160mm	Analysis 3
Size	5F~8F	5F~8F	Identical
Guidewire Diameter	0.018”, 0.021”	0.038”, 0.021”,0.025”	Analysis 4
Guidewire length	45cm	45cm	Identical
Needle	21G	18G, 21G, 20G	Analysis 5
Dilator length	110mm, 130mm, 170mm	168mm, 218mm	Analysis 6
Package Content	Sheath Introducer, Dilator, Guidewire, Introducer Needle	Sheath Introducer, Dilator, Guidewire, Needle or I.V.Cannula	Identical
Material			
Sheath tube	Fluorinated Ethylene Propylene (FEP)	Fluorinated Ethylene Propylene (FEP)	Identical
Sheath Hub	Copolyester	Copolyester	Identical
Side Port Tubing	Polyvinylchloride(PVC) Polyurethane (PU)	Polyvinylchloride(PVC) Polyurethane (PU)	Identical
Hemostasis Valve	Silicon	Silicon	Identical
3-Way Stopcock Body	Polycarbonate (PC)	Polyethyene (PE)	Analysis 7
Stopcock Cap	High Density Polyethylene (HDPE)	Polycarbonate (PC)	Analysis 7
Stopcock Valve core	High Density Polyethylene (HDPE)	Polyethyene (PE)	Analysis 7

Dilator Tube	Polypropylene (PP)	Polypropylene (PP)	Identical
Dilator Hub	Acrylonitrile-butadiene-styrene (ABS)	Acrylonitrile-butadiene-styrene (ABS)	Identical
Guidewire	NiTi, Stainless Steel	Stainless Steel, Nickel Titanium Alloy	Identical
Needle hub	Glue Q	Acrylonitrile-butadiene-styrene (ABS), PC	Analysis 7
Needle Tube	Stainless Steel	Stainless Steel	Identical
Protect Cover	Polypropylene (PP)	PP, PE	Analysis 7
Sterilized Method	EO	EO	Identical
Sterility level	SAL 10^{-6}	SAL 10^{-6}	Identical

INT Introducer set is substantially equivalent in design, raw material, indication for use, package, sterilization method to the predicate devices, KDL introducer set. The differences were addressed using appropriate testing as follows.

8. Performance data

All necessary bench and non-clinical testing was conducted on introducer set to support a determination of substantial equivalence to the predicate device.
The non-clinical, bench testing were conducted according to ISO 11070: 2014, ISO 80369-7:2016 and ISO 9626:2016:

No.	Testing item	
1	Sheath introducer	Appearance
2		O.D and I.D
3		Effective length
4		Sheath hub
5		Sheath introducer leakage
6		Hemostasis valve leakage
7		Peak tensile force
9	Dilator	Appearance
10		O.D and I.D
11		Effective length
12		Dilator hub
13		Strength of union
15	Guidewire	Appearance
16		O.D.
17		Effective length
18		Corrosion resistance
19		Fracture test
20		Flexing test
21		Peak tensile force
22		Torque strength
23		Torqability
24		Tip flexibility
25	Introducer needle	Appearance
26		O.D and I.D.

27		Effective length
28		Corrosion resistance
29		Luer connector
30		Strength union
31		Needle point
32		Patency
33		Stiffness
34		Breakage resistance
35	INT introducer set	Compatibility test
36		Radio-detectability
37		Particulate
38		EO residual
39		limits for acidity and alkalinity(PH)
40		Sterility
41		Bacterial Endotoxin (LAL test)

9. Sterilization and Shelf Life

Sterilization and Shelf-Life Testing were performed on the proposed device:

EO residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP <85>
Visual Inspection test	ASTM F1886-2016
Seal Strength test	ASTM F 88/F88M-2015
Dye penetration test	ASTM F 1929
Shelf-Life Evaluation	Physical, Mechanical, Chemical, Package Tests were performed on aging samples to verify the claimed shelf life of the device.

10. Clinical Test

No clinical study is included in this submission

11. 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 below test items.

Table 12-1 Biocompatibility tests

Items	Standards	Conclusion
In Vitro hemolytic	ASTM F756-17	The test result showed the device had no influence on hemolytic properties.
Acute System Toxicity	ISO 10993-11:2017	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 Cytotoxicity	ISO 10993-5:2009	Under the conditions of this study, the test article Micro catheter 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 10993-10:2010	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 10993-11:2017	No rabbit an individual rise in temperature of 0.5℃ or more.
In vivo thrombogenicity	ISO 10993-4:2017	Meet the requirement of in vivo thrombogenicity test.
Complement activation	ISO 10993-4:2017	No influence on complement activity.

The subject device, INT introducer set is subject to biocompatibility test in accordance with ISO 10993-1, the test results demonstrate that INT Introducer set is substantially equivalent to the predicate.

12. Conclusion

The nonclinical tests demonstrated that the device was substantially equivalent to the predicate device.