



September 13, 2018

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

Re: K180177
Trade/Device Name: Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
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,

Lydia S. Glaw -S

2018.09.13 15:51:20 -04'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K180177

Device Name

Guidewire

Indications for Use (Describe)

Guidewire is intended to be used in the coronary and/or peripheral vascular system to introduce and position catheters to desired anatomical location during diagnostic or 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.

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
PRASStaff@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."

Section 3- 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: **K180177**

1. Date of Submission: Jan.22, 2018

2. Submitter

Shanghai Kindly Medical Instruments Co., Ltd.
No. 925, Jinyuan yi Road, Shanghai, 201803, China
Establishment Registration Number: 3009605245
Contact Person: Xu Jianhai
Position: RA Supervisor
Tel.:+086-021-59140056
Fax: +086-021-59140056
Email: xujianhai@kdlchina.net

3. Proposed Device

Proposed Device Name: Guidewire
Review Panel: Cardiovascular
Regulation Number: 21 CFR 870.1330.
Regulation name: Catheter guide wire
Regulation Class: Class II
Product Code: DQX

4. Predicate device

- a. 510(k) Number: K141295
Product Name: Merit Hydrophilic Guide Wire
Manufacturer: Merit Medical Systems, Inc.
- b. 510(k) Number: K133230
Product Name: InQwire®
Manufacturer: Merit Medical Systems, Inc.

5. Device description

The Guidewire are designed to facilitate the placement of interventional devices. The guidewire has two models, PTFE coating type and hydrophilic coating type. The two models have the

different material for wire and coating. PTFE guidewire consists of stainless steel spring coil wire, inside core wire and a safety wire. The guidewire is placed inside a loop flush dispenser, also as a hoop. Hydrophilic guidewire consists of nickel titanium alloys core wire with a jacket that has a hydrophilic coating. The guidewire is placed inside a spiral hoop. The Guidewire is radiopactive under fluoroscopy. The wire will be offered in straight, angle, J-tip configuration . All guidewires are available in five nominal outer diameter of 0.025”, 0.028”, 0.032”, 0.035”, 0.038” inches and nominal lengths of 100cm, 150cm, 180cm, and 260cm.

6. Intended Use Statement:

Guidewire is intended to be used in the coronary and/or peripheral vascular system to introduce and position catheters to desired anatomical location during diagnostic or 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, and no new issues of safety and effective were raised with the testing performed.

The following performance tests have completed per the ISO standards, in house standard and/or FDA guidance :

Testing item	Reference Standard	Conclusions
Appearance	Section 4.3 of ISO 11070:2014	The predetermined acceptance criteria was met
O.D.	Section 8.2 a) of ISO 11070:2014	The predetermined acceptance criteria was met
Length	Section 8.2 b) of ISO 11070:2014	The predetermined acceptance criteria was met
Corrosion resistance	Section 4.4 ISO 11070:2014	The predetermined acceptance criteria was met
Fracture test	Section 8.4 of ISO 11070:2014	The predetermined acceptance criteria was met
Flexing test	Section 8.5 of ISO 11070:2014	The predetermined acceptance criteria was met
Peak tensile force	Section 8.6 of ISO 11070:2014	The predetermined acceptance criteria was met
Toque strength	3b of FDA Guidance for Coronary and Cerebrovascular Guidewire	The predetermined acceptance criteria was met

	Guidance 1995	
Torqueability	3c of FDA Guidance for Coronary and Cerebrovascular Guidewire Guidance 1995	The predetermined acceptance criteria was met
Tip flexibility	3d of FDA Guidance for Coronary and Cerebrovascular Guidewire Guidance 1995	The predetermined acceptance criteria was met
Particulate test	In-house standard	The predetermined acceptance criteria was met
Coating Friction force	In-house standard	The predetermined acceptance criteria was met
Coating Integrity	In-house standard	The predetermined acceptance criteria was met
Radio-detectability	ASTM F640-12	The predetermined acceptance criteria was met
EO residual	ISO 10993-7:2008/Cor1:2009.	The predetermined acceptance criteria was met
Sterility	ISO 11737-1	The predetermined acceptance criteria was met
Bacterial Endotoxin (LAL test)	USP <85>	The predetermined acceptance criteria was met

Per ISO 10993-1:2009, the proposed device is classified as external communication devices in contact with circulating blood for a limited (≤ 24 hours) duration. The following biocompatibility test were completed and the biocompatibility was acceptable:

- In Vitro Hemolytic
- In Vitro Cytotoxicity
- Intracutaneous Reactivity
- Skin Sensitization
- Acute Systemic Toxicity
- Pyrogen
- In Vivo Thrombogenicity
- Complement Activation

8. Clinical Test

It is not applicable

9. Summary Comparing the Technological Characteristics

In accordance with the recognized consensus ISO standard and FDA guidance document, performance test was conducted to ensure the performance characteristic of the proposed device. Comparisons of the proposed and predicate devices show that the intended use , classification, principle of operation, main materials, performance characteristics, sterilization method, sterility level and packaging are identical or substantially equivalent to the currently marked predicate devices. Please refer to the table.

Item	Proposed Device	Predicate Device		Remark
		K141295	K133230	
Product Code	DQX	DQX	DQX	Same
Regulation No.	21 CFR 870.1330	21 CFR 870.1330	21 CFR 870.1330	Same
Class	II	II	II	Same
Intended Use	Guidewire is intended to be used in the coronary and/or peripheral vascular system to introduce and position catheters to desired anatomical location during diagnostic or interventional procedures.	The Merit Hydrophilic Guide Wire is intended to be used in the peripheral vascular system to facility the placement of devices during diagnostic and interventional procedure.	The Merit Guide Wire are used to facility the placement of devices during diagnostic and interventional procedure.	Same
Principle of Operation	The guidewire is manually inserted into a vessel and advance to the target region	The guidewire is manually inserted into a vessel and advance to the target region	The guidewire is manually inserted into a vessel and advance to the target region	Same
Package contents	Guiewire, straighter, hoop dispenser	Guiewire, straighter, hoop dispenser	Guiewire, straighter, hoop dispenser	Same
Design Description	The PTFE coating guide wire consist of a PTFE coated a coil wire, with an inside core wire and safety wire. The core wire extends the full length of the coil wire. The hydrophilic coating wire consist of a jacketed core wire	The Merit Hydrophilic Guide wire is jacketed core wire with a hydrophilic coating applied to the jacket.	The guidewire have a continuous PTFE coated coil, inside core wire and a safety wire. The core wie is fixed at the proximal end only and extends to a specified distance from the distal	Same

	with hydrophilic coating. The core wire is made of Ninickel titanium alloys.		end.	
Outer diameter	0.025”, 0.028”, 0.032”, 0.035”, 0.038”	0.018”, 0.025”, 0.035”, 0.038”	0.035”, 0.038”	Device size more than predicate device
Hydrophilic coating	Hydrophilic coating and PTFE coating	Hydrophilic coating	PTFE coating	Same
Tip configuration	Straight, J-tip and angel.	Straight, angled, standard and stiff	Straight or J-tip	Similar
Material	Stainless steel, Ninickel titanium alloys	Ninickel titanium alloys	Stainless steel	Same
Jacket material	TPU with tungsten powder	unkown	unkown	The material have no risk for intended clinical use
Sterilization Method	EO	EO	EO	Same
Sterility Assurance Level	10 ⁻⁶	10 ⁻⁶	10 ⁻⁶	Same

10. Conclusion

In summary, a battery testing was conducted in accordance with protocols based on requirements outline in guidance’s and standards and these were shown to meet the acceptance criteria that were determined to demonstrated substantial equivalence. There are no significant difference that raise any new issues of safety and effectiveness.