August 26, 2020

Suzhou Hengrui Disheng Medical Co., Ltd.
Ling Li
Regulatory Affairs Manager
No. 11 Building, No.8 Jinfeng Road
Suzhou 215163, China

Re: K193653
Trade/Device Name: Hydrophilic Coating Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: July 20, 2020
Received: July 27, 2020

Dear Ling Li:

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 Lydia Glaw
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K193653

Device Name
Hydrophilic Coating Guide Wire

Indications for Use *(Describe)*

The Hydrophilic Coating Guide Wire is designed to direct a catheter to the desired anatomical location in the peripheral and coronary vasculature during diagnostic or interventional procedures. This device is not intended for neurovascular interventions.

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

Submitter:	Suzhou Hengrui Disheng Medical Co., Ltd No. 11 Building No. 8 Jinfeng Road, Suzhou, China Phone: +86- 512-6805-0607 Fax: +86- 512-6680-6133
Contact Person:	Ling Li Regulatory Affairs Manager Phone: +86- 512-6805-0607 Fax: +86- 512-6680-6133 Email: liling02@hrmedical.com.cn

Date prepared:	August 4, 2020
Trade Name:	Hydrophilic Coating Guide Wire
Common Name:	Guide wire
Classification Name:	Wire, Guide, Catheter
Classification Panel:	Cardiovascular Devices
Regulation Number:	21CFR Part 870.1330
Product Code:	DQX
Classification:	Class II
Predicate device:	Acme Monaco Slidewire® (K113162)
Reference Device:	Terumo Radifocus Guide Wire (K863138)

Device Description:

The Hydrophilic Coating Guide Wire consists of a Nickel-Titanium alloy core wire; a polymer jacket (Polyurethane containing Tungsten for X-Ray visibility); and a hydrophilic coating applied to the entire wire. There are two shaft configurations: standard and stiff. There are two distal tip shapes: straight and angled. The guide wire is provided sterile (EtO) and is intended for single use only.

Intended Use:

The Hydrophilic Coating Guide Wire is designed to direct a catheter to the desired anatomical location in the peripheral and coronary vasculature during diagnostic or interventional procedures. This device is not intended for neurovascular interventions.

Substantial Equivalence Comparison:

The Hydrophilic Coating Guide Wire was found to be substantially equivalent to the predicate device Acme Monaco Slidewire® (K113162) and reference device Terumo Radifocus Guide Wire (K863138). A comparison of the technological characteristics is summarized on the table below:

Table 1 Summary of Comparative Information

Description	Subject Device: Hydrophilic Coating Guide Wire Guide Wire	Predicate Device: Acme Monaco Slidewire	Reference Device: Radifocus Guide Wire	Remark
510(k) Number	K193653	K113162	K863138	N/A
Manufacturer	Suzhou Hengrui Disheng Medical Co., Ltd	Acme Monaco Corporation	Terumo Medical Corporation	N/A
Classification	II	II	II	Same
Product Code	DQX	DQX	DQX	Same
Regulation	21 CFR Part 870.1330	21 CFR Part 870.1330	21 CFR Part 870.1330	Same
Indications for use	Designed to direct a catheter to the desired anatomical location in the peripheral and coronary vasculature during diagnostic or interventional procedures. This device is not intended for neurovascular interventions.	Intended for use in diagnostic or interventional procedures to assist in directing a catheter to the desired anatomical location in the coronary or peripheral vasculature.	Designed to direct a catheter to the desired anatomical location during diagnostic or interventional procedures.	Same with predicate device
Operation Principle	Manual	Manual	Manual	Same
Core wire	Nickel Titanium	Nickel Titanium	Nickel Titanium	Same
Jacket	Polyurethane	Polyurethane	Polyurethane	Same
Radiopaque	Tungsten	Tungsten	Tungsten	Same

Description	Subject Device: Hydrophilic Coating Guide Wire Guide Wire	Predicate Device: Acme Monaco Slidewire	Reference Device: Radifocus Guide Wire	Remark
Coating	Hydrophilic Caoting	Hydrophilic Caoting	Hydrophilic Caoting	Same
Specification	Diameter: 0.032",0.035",0.038" Length: 150cm, 180cm, 260cm	Diameter: 0.014"- 0.052" Length: 30cm - 300cm	Diameter: 0.018"- 0.052" Length: 30cm - 300cm	Within the range of predicted device specification
Usability	Single use	Single use	Single use	Same

Biocompatibility Testing:

Biocompatibility testing was performed to ensure the material safety in accordance with the tests recommended in the I*nternational Standard ISO 10993-1. "Biological Evaluation of Medical Devices Part-I: Evaluation and testing within a risk management process."* The wire is classified as an Externally Communicating Device, Circulating Blood, Limited Contact (≤24h). The following biocompatibility tests were completed and the biocompatibility was acceptable:

- Cytotoxicity
- Sensitization (Kligman Maximization)
- Irritation / Intracutaneous Reactivity
- Acute Systemic Toxicity
- Pyrogen
- Hemolysis test(extract method)
- Thrombosis test
- Partial Thromboplastin Time (PTT) test
- Prothrombin time (PT) test

Non-Clinical Performance Testing:

Performance testing has been conducted in accordance with FDA guidance document *Coronary and Cerebrovascular Guidewire Guidance, January 1995; Coronary, Peripheral, and Neurovascular Guidewire-Performance Tests and Recommended Labeling, Draft Guidance for Industry and Food and Drug Administration Staff, June 15, 2018; ISO 11070:2014, Sterile Single-use Intravascular Introducers, Dilators And Guidewires.* The tests included the following:

- Size and Surface
- Tensile Strength
- Torque Strength
- Torqueability
- Coating Integrity
- Particulate Evaluation
- Lubricity
- Kink Resistance
- Tip Flexibility
- Radiopacity
- Fracture test
- Flexing test
- EO and ECH residual
- Sterile Bacterial endotoxin
- Visual Inspection of the inner pouch
- Dye leakage test of the inner pouch
- Sealing-strength of the inner pouch

Conclusion:

The Hydrophilic Coating Guide Wire was found to be substantially equivalent in its design, intended use, technology, principal of operation, and performance to the predicate device. There are not significant differences between the Hydrophilic Coating Guide Wire and the predicate device that raise new issues of safety and effectiveness.