July 29, 2020

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

Re: K193647
Trade/Device Name: Superpipe Angiographic Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: June 15, 2020
Received: June 22, 2020

Dear Li Ling:

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,

Gregory O'Connell
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193647

Device Name
SUPERPIPE Angiographic Catheter

Indications for Use *(Describe)*
The SUPERPIPE Angiographic Catheter is intended for use in angiographic procedures. It delivers radiopaque media, guide wires, catheters, and therapeutic agents to selected sites in the 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

Submitter: Suzhou Hengrui Disheng Medical Co., Ltd
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Date Prepared: June 15, 2020

Trade Name: SUPERPIPE Angiographic Catheter

Common Name: Diagnostic Intravascular Catheter

Classification: Class II, 21 CFR Part 870.1200

Product Code: DQO

Predicate Device: K992051 - Radifocus Optitorque Angiographic Catheter (Terumo Medical Corp.)
This predicate device has not been subject to a design-related recall.

Device Description: Angiographic Catheter consists of a catheter hub, a strain relief tubing, catheter shaft (including braided section and non-braided section) and catheter tip. It is comprised of a two-layer construction featuring stainless steel mesh sandwiched between layers of polyamide elastomers of the catheter braided section. The non-braided section is comprised of layers of polyamide elastomers. And the soft catheter tip is comprised of the mixture of polyurethane and polyamide elastomers. The device is offered in lengths of 80cm, 100cm and 110cm.

Indications for Use: The SUPERPIPE Angiographic Catheter is intended for use in angiographic procedures. It delivers radiopaque media, guide wires, catheters, and therapeutic agents to selected sites in the vascular system.

Comparison with Predicate Device: The subject devices and predicate device have identical / similar technological characteristics as shown in the following table.

Description	Subject Device: Angiographic Catheter	Predicate Device : Radifocus Optitorque
510(k) Number	K193647	K992051
Manufacturer	Suzhou Hengrui Disheng Medical Co., Ltd	Terumo Medical Corp.
Classification	II	II
Product Code	DQO	DQO
Regulation	21 CFR 870.1200	21 CFR 870.1200
Indications for Use	The SUPERPIPE Angiographic Catheter is intended for use in angiographic procedures. It delivers radiopaque media, guide wires, catheters, and therapeutic agents to selected sites in the vascular system.	The Radifocus Optitorque is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the vascular system.
Operation Principle	Manual	Manual
Catheter Effective Length	80cm 100cm 110cm	65-120 cm
Catheter Outer Diameter	4Fr / 1.40mm 5Fr / 1.70mm 6Fr / 2.00mm	4Fr / 1.40mm 5Fr / 1.70mm 6Fr / 2.00mm
Catheter Inner Diameter	4Fr / 1.05mm 5Fr / 1.13mm, 1.20mm 6Fr / 1.20mm, 1.30mm	4Fr / 1.05mm 5Fr / 1.22mm 6Fr / 1.32mm
Guide wire Compatibility	0.038″(0.97mm)	0.038″(0.97mm)
Sterilization	Sterile / Ethylene oxide	Sterile / Ethylene oxide

Description	Subject Device: Angiographic Catheter	Predicate Device : Radifocus Optitorque
Usability	Single use	Single use
Catheter Body	**Shaft:** **Inner Layer:** Polyamide elastomer **Braid:** Stainless steel **Outer Layer:** Polyamide Elastomer	**Shaft:** **Inner Layer:** Polyamide elastomer, Polyurethane elastomer **Braid:** Stainless steel **Outer Layer:** Polyamide elastomer, Polyurethane elastomer
	Tip: Polyamide Elastomer, Polyurethane elastomer	**Tip:** Polyurethane elastomer
	Strain relief tubing: LLDPE **Catheter hub:** Polyethylene terephthalate -1, 4-cyclohexanedimethanol ester	**Strain relief:** Polyurethane elastomer **Hub:** Polyamide

The SUPERPIPE Angiographic Catheter is substantially equivalent to the Radifocus Optitorque Angiographic Catheter in technology/principal of operation is similar in the material and design. The main differences between the Angiographic Catheter and the predicate device are the size and the material. These differences do not raise any significant issues of safety or effectiveness. Performance (bench) testing and biocompatibility testing were performed to demonstrate that the proposed device performs as intended and does not raise new questions of safety or efficacy compared to the predicate devices.

Performance Data: The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Performance Testing

Performance testing was performed per ISO 10555-1. The test items, methods and method references of Superpipe Angiographic Catheter are as follows:

- Catheter Sizes

- Catheter Surface
- Catheter Color
- Side Holes
- Catheter Hub
- Distal Tip
- Distal Shape
- Freedom from Leakage
- Peak Tensile Force of Catheter
- Burst Pressure under Static Conditions
- Radio-detectability
- Torsion Transmissibility
- Torque strength
- Kink test
- Push and withdrawal Ability
- Simulated Use
- Flow rate
- EO and ECH Residual
- Sterile
- Bacterial Endotoxin
- Visual Inspection test of the inner pouch
- Sealing-strength of the Inner Pouch
- Dye Leakage Test of the Inner Pouch

Biocompatibility Testing

Biocompatibility evaluation for the Angiographic Catheter was conducted in accordance with current standards and the following tests were included:

- Cytotoxicity study
- Sensitization study
- Intracutaneous study
- Acute systemic toxicity study
- Pyrogen study
- Hemolysis study
- In-vivo thromboresistance study
- Complement activation assay

Conclusion: The Angiographic Catheter 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 Angiographic Catheter and the predicate device that raise new issues of safety and effectiveness.