April 11, 2022

Suzhou Hengrui Hongyuan Medical Co., Ltd
Wang Peipei
Regulatory Affairs Manager
Building B9 Unit 201, No. 218 Xinghu Road, SIP
Suzhou, Jiangsu 215126
China

Re: K212719
Trade/Device Name: Micro Catheter and Guidewire System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: March 3, 2022
Received: March 14, 2022

Dear Wang Peipei:

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

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212719

Device Name
Micro Catheter and Guidewire System

Indications for Use *(Describe)*
The Micro Catheter and Guidewire System is intended for the infusion of contrast media into the peripheral vessels. The Micro Catheter and Guidewire system is also intended for drug infusion in intra-arterial therapy and the infusion of embolic materials for hemostasis. The system should not be used in cerebral vessels.

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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K212719

510(k) Summary

Micro Catheter and Guidewire System

(per 21 CFR 807.92)

Submitter:	Suzhou Hengrui Hongyuan Medical Co., Ltd Building B9 Unit 201, No. 218 Xinghu Road, SIP, Suzhou, Jiangsu, China
Contact Person:	Wang peipei Regulatory Affairs Manager Phone：+86-512-6835-6665 Email: wangpeipei@hrmedical.com.cn
Date Prepared:	August 18th, 2021
Trade Name:	Micro Catheter and Guidewire System
Common or Usual Name:	Continuous flush catheter
Classification:	Class II, 21 CFR Part 870.1210
Product Code:	KRA
Predicate Device:	K171665- Micro Catheter and Guidewire System (Suzhou Hengrui Disheng Medical Co., Ltd)
Reference Devices:	K033913- Progreat™ Angiographic Catheter (Terumo Medical Corporation) K172081- Maestro Micro catheter (Merit Medical Systems) K080863- Traxcess 0.014'' Hydrophilic Guidewire (Micro Vention, Inc) K993672- Rebar™ Micro Catheter(Micro Therapeutics,Inc.)

Device Description:	Micro Catheter and Guidewire System consists of a catheter, a guidewire, and accessories. The accessories include a flushing device, a shaping mandrel, an insertion tool, a torque device and a peel-able tube. The catheter is consist of a hub, a stress relief tube and a catheter shaft. The catheter shaft has three layers. The inner layer is a PTFE tube, the middle layer is consist of stainless steel wire reinforce and platinum-iridium alloy radiopaque distal marker. And the outer layer is polyamide. There is also a hydrophilic coating on the catheter surface. The guidewire is consist of a nitinol core, a polymer jacket with PVP hydrophilic coating over its entire surface, and a spring coil at distal. It has a white marker at the proximal to indicate the length inserted into human body and its relative position with the catheter.
Indications for Use:	The Micro Catheter and Guidewire System is intended for the infusion of contrast media into the peripheral vessels. The Micro Catheter and Guidewire system is also intended for drug infusion in intra-arterial therapy and the infusion of embolic materials for hemostasis. The system should not be used in cerebral vessels.
Comparison with Predicate Device:	The Micro Catheter and Guidewire System is similar to the Micro Catheter and Guidewire System in following ways: • Each of the devices is intended to be used for the infusion of contrast media into all peripheral vessels, drug infusion in intra-arterial therapy and the infusion of embolic materials for hemostasis. • Each of the devices is provided with catheter, guidewire and accessories. • Each of the devices is provided sterile. • Each of the devices is intended to be single use. • Each of the devices has a hydrophilic coating. • Each of the catheter has a platinum-iridium alloy radiopaque marker. • Each of the catheter has the same raw materials. • Each of the guidewire has the same structure. • Each of the guidewire has the same raw materials. The following technological differences exist between the subject and predicate devices: • Catheter outer diameter • Catheter effective length

- Guidewire effective length
- Accessories

Performance Data:

Biocompatibility Testing

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

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute systemic Toxicity
- Pyrogenicity
- Hemolysis study
- Partial Thromboplastin time
- Complement Activiation
- Thrombogenicity

Bench Testing

The tests included the following:

- Catheter Sizes
- Catheter Surface
- Catheter Hub
- Peak tensile force of catheter
- Coating test of catheter
- Freedom from leakage
- Distal tip of catheter
- Torque Strength of catheter
- Kink resistant of catheter
- Radiopacity of catheter
- Hydration judgment of catheter
- Burst pressure under static conditions
- Guidewire Sizes
- Guidewire surface
- Coating test of guidewire
- Peak tensile force of guidewire
- Torque strength testing of guidewire
- Torqueability test of guidewire
- Kink resistance of guidewire
- Simulated Use
- Tip flexibility of guidewire

- Radio-detectability of guidewire
- Sterile
- Bacterial endotoxin
- Particulate test

Conclusion: The data provided of the Micro Catheter and Guidewire System and the mechanical testing results demonstrate that the device should perform as intended in the specified use conditions. Non-clinical tests demonstrate that the Micro Catheter and Guidewire System is substantially equivalent to the predicate device which is currently marketed for the same intended use.