January 11, 2018

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

Re: K171665
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: December 8, 2017
Received: December 13, 2017

Dear Jingwen 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K171665

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 vasculature. The Micro Catheter and Guidewire system is also intended for drug infusion in intra-arterial therapy and the infusion of embolic materials for hemostasis.

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:

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Contact Person:

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Date Prepared: May 22nd, 2017

Trade Name: Micro Catheter and Guidewire System

Common Name: Continuous flush catheter

Classification: Class II, 21 CFR Part 870.1210

Product Code: KRA

Predicate Device: K033913 - Progreat™ Micro Catheter system (Terumo Medical Corporation)

Reference Devices: K101450 - Cantata ™ Microcatheter (Cook Incorporated.)
K052841 - Mira-Flex™ 18 Micro catheter (Cook Incorporated.)

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, and a torque device.

The catheter is consist of a hub, a stress relief tube and a catheter body. The catheter body 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 polyamides of different hardness mixed with pigment. There is also a hydrophilic coating on the catheter surface.

The guidewire is consist of a nitinol core, a polymer jacket with hydrophilic coating over its entire surface and a radiopaque distal marker. It has a white marker at the proximal end 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 vasculature. The Micro Catheter and Guidewire system is also intended for drug infusion in intra-arterial therapy and the infusion of embolic materials for hemostasis.

Comparison with Predicate Device: The Micro Catheter and Guidewire System is similar to the Progreat Micro Catheter 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 compatible with 5Fr Guide Catheter.
- 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 devices has a platinum-iridium alloy radiopaque marker.

The following technological differences exist between the subject and predicate devices:

- Effective length
- Available outer/inner diameter of the catheter
- Accessories
- Guidewire Hub
- Proximal marker of guidewire
- Materials of Hydrophilic coating, catheter body, catheter hub

Performance Data: <u>Biocompatibility Testing</u>

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
- Systemic Toxicity
- Pyrogenicity
- Hemolysis study
- In-vivo thromboses study
- Complement Activiation

Bench Testing

Mechanical testing was performed per ISO 10555.1 and ISO 11070. The tests included the following:

- Catheter Sizes
- Catheter Surface
- Catheter Hub
- Coating Integrity/Adherence of catheter
- Peak tensile force of catheter
- Freedom from leakage
- Distal tip of catheter
- Torque Strength of catheter
- Kink resistant of catheter
- Radio-detectability of catheter
- Hydration judgment of catheter
- Burst pressure under static conditions
- Guidewire Sizes
- Guidewire surface
- Coating Integrity/Adherence of guidewire
- Fracture test of guidewire
- Flexing test of guidewire
- Bending force of guidewire
- Peak tensile force of guidewire
- Torque strength testing of guidewire
- Tip rigidity of guidewire
- Radio-detectability of guidewire
- Surface of flushing device
- Finger grips of flushing device
- Piston of flushing device
- Nozzle of flushing device
- Limits for extractable metals

- Limits for acidity or alkalinity
- Reducing substances
- Size of torque device
- Surface of torque device
- Use performance of torque device
- Lock adapter of the torque device
- Sizes of insertion tool
- Surface of insertion tool
- Connection strength of the needle and hub of insertion tool
- Corrosion resistance of the insertion tool
- Size of shaping mandrel
- Surface of shaping mandrel
- Corrosion resistance of shaping mandrel
- Push and withdrawal ability of the system
- Simulated use of the system
- Torsion transmissibility of the system
- EO and ECH residual
- Sterile
- Bacterial endotoxin
- Dye leakage test of the inner pouch
- Sealing-strength of the inner pouch

Conclusion: The data provided demonstrate that the Micro Catheter and Guidewire System is substantially equivalent to the predicate device which is currently marketed for the same intended use.