February 10, 2022

Shanghai Heartcare Medical Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
China

Re: K202926
Trade/Device Name: Micro Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: January 8, 2022
Received: January 11, 2022

Dear Diana Hong:

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,

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K202926

Device Name
Micro Catheter

Indications for Use *(Describe)*
The Micro Catheter is intended for selective delivery of therapeutic devices and infusion of contrast media into the peripheral and neuro vasculature.

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

This 510(k) Summary is being submitted in accordance with requirements of 21 CFR 807.92.

510(k) Number: K202926

Date of Preparation: 02/10/2022

1. Sponsor Identification

Shanghai Heartcare Medical Technology Co., Ltd.
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2. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
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3. Identification of Proposed Device

Trade Name: Micro Catheter
Common Name: Intravascular Catheter

Regulatory Information

Primary Product Code
Classification Name: Catheter, Percutaneous, Neurovasculature
Classification: II
Product Code: QJP
Regulation Number: 21CFR 870.1250
Review Panel: Neurology

Secondary Product Code
Classification Name: Catheter, Percutaneous
Classification: II
Product Code: DQY
Regulation Number: 21CFR 870.1250
Review Panel: Cardiovascular

4. Identification of Predicate Device and Reference Devices

Predicate Device
510(k) Number: K192122
Product Name: Trevo Trak 21 Microcatheter

Reference Device 1
510(k) Number: K993672
Product Name: Rebar Micro Catheter

Reference Device 2
510(k) Number: K001966
Product Name: Rebar Micro Catheter

5. Device Description

The proposed device Micro Catheter is a single-lumen catheter designed to be introduced over a steerable guidewire into the peripheral and neuro vasculature. The proximal end of the catheter incorporates standard Luer adapter to facilitate the attachment of accessories. The outer surface of the catheter has a lubricious coating at the distal end of the Micro Catheter. The catheter has a radiopaque marker at the distal end to facilitate fluoroscopic visualization. The device is intended for single use and is provided sterile.

6. Indications for Use

The Micro Catheter is intended for selective delivery of therapeutic devices and infusion of contrast media into the peripheral and neuro vasculature.

7. Comparison of Technological Characteristics

Table 1 Comparison of Technological Characteristics

Item	Subject Device	Predicate Device K192122	Reference Device 1 K993672	Reference Device 2 K001966
Classification	II	II	II	II
Product Code	QJP, DQY	DQO, DQY	KRA	KRA
Regulation Number	21 CFR 870.1250	21 CFR 870.1200 21 CFR 870.1250	21 CFR 870.1210	21 CFR 870.1210
Indication for Use	The Micro Catheter is intended for selective delivery of therapeutic devices and infusion of contrast media into the peripheral and neuro vasculature.	The Microcatheter is indicated for use in the selective placement of devices and/or fluids, such as contrast media, into the peripheral, coronary, and neuro vasculature during diagnostic and/or therapeutic procedures.	The Rebar Micro Catheter is intended for the controlled selective infusion of physician-specified therapeutic agents or contrast media into the vasculature of the peripheral and neuro anatomy.	The Rebar Micro Catheter is intended for the controlled selective infusion of physician-specified therapeutic agents or contrast media into the vasculature of the peripheral and neuro anatomy.
Component	Ruhr Handle Outer Stress Tube Inner Stress Tube Coil Tube	Outer Jacket Shaft Braid Strain Relief Inner Layer Catheter Hub	Ruhr Handle Outer Stress Tube Inner Stress Tube Coil Tube	Ruhr Handle Outer Stress Tube Inner Stress Tube Coil Tube
Inner Diameter	0.021, 0.027 inch	0.021 inch	0.027 inch	0.021 inch
Proximal Outer Diameter	2.85 Fr (0.95 mm)	2.85 Fr (0.95 mm)	2.8 Fr (0.93 mm)	2.8 Fr (0.93 mm)
Distal Outer Diameter	2.55 Fr (0.85 mm), 2.85 Fr (0.95 mm)	2.4 Fr (0.80 mm), 2.0 Fr (0.67 mm)	2.8 Fr (0.93 mm)	2.3 Fr (0.76 mm)
Effective length	110, 130, 145, 153 cm	162 cm	110, 130, 145 cm	110, 130, 153 cm

Maximum Guidewire	0.010 inch	0.018 inch	0.021 inch	0.018 inch
Radiopaque Marker	Yes	Yes	Yes	Yes
Single Use	Yes	Yes	Yes	Yes
Materials				
Inner Layer of Coil Tube	Polytetrafluoroethylene	PTFE	Polytetrafluoroethylene	Polytetrafluoroethylene
Outer Layer of Coil Tube	Pebax	Polyolefin	Pebax	Pebax
Coating	Polyvinylpyrrolidone (PVP)	Hydrophilic Coating	Hyaluronic Acid	Hyaluronic Acid
Radiopaque Marker	Platinum-iridium alloy	Platinum/iridium	Platinum-iridium alloy	Platinum-iridium alloy
Ruhr Handle	Polycarbonate (PC)	Polyurethane	unknown	unknown
Adhesive	Dymax 204-CTH-F	Acrylic (Acrylated Urethane)	unknown	unknown

8. Non-Clinical Performance Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications and was substantially equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-3: 2014 Biological evaluation of medical devices-Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-4: 2017 Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood
- ISO 10993-5: 2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity
- ISO 10993-7: 2008 Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals
- ISO 10993-10: 2010 Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
- ISO 10993-11: 2017 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity
- USP <85> Bacterial Endotoxins Test
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88/88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ISO 594-1: 1986 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements
- ISO 594-2: 1998 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings
- ISO 10555-1: 2013 Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements
- ISO 80369-7: 2106 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

The results of verification and validation testing conducted on the Micro Catheter demonstrate that it performs as designed and is suitable for its intended use. A summary of the tests performed is provided in the table below:

Test	Test Method Summary	Results and Conclusion
Surface Evaluation	Observe the catheter by eye or under microscope at X 2.5 magnification for any structural or mechanical damage.	Surface met acceptance criteria.
Radiopacity	The radiopaque marker on the catheter tip should be visible under X - ray.	The radiopaque marker on the catheter tip is visible under X-ray.

Dimensional verification	Verify dimensions using specified measurement tools. Record measurements.	Size verification met acceptance criteria.
Liquid leakage	The proposed device was evaluated per ISO 10555-1 to demonstrate that the device meets the liquid leakage under pressure requirements.	No liquid leakage.
Static burst pressure	Burst pressure tests were performed at pressures greater than the manual syringe injection pressures.	Burst pressure met acceptance criteria.
Peak tensile force	Use a tensile test machine to apply a tensile load to the sample and determine whether the maximum tensile force meets the acceptance criteria.	Peak tensile force met acceptance criteria.
Torque Strength	Fix the distal end of the catheter and rotate the proximal end until the failure. Record the number of rotation and the failure mode.	Torque strength met acceptance criteria.
Torqueability	Rotate the proximal end of the catheter 90 degrees to observe the distal end of the catheter and calculate a proximal-to-distal rotational ratio for the device.	Torqueability met acceptance criteria.
Kink resistance	The proposed device was evaluated per FDA guidance "Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems", section IV, C.9.	Kink resistance met acceptance criteria.
Trackability	The proposed device was evaluated per FDA guidance "Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems", section IV, C.2.	Trackability met acceptance criteria.
Particulate testing	After simulated use testing with compatible devices, determine the quantity and size of the particles generated.	The number and size of the particles were similar to that of the predicate device.
Coating integrity	After simulated use testing with compatible devices, the coating is dyed and checked for coating defects at X 500 magnification.	Coating integrity met acceptance criteria.

Tip flexibility	The proposed device was evaluated per FDA guidance "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling", section IV, G.15.	Tip flexibility met acceptance criteria.
Air leakage	The proposed device was evaluated per ISO 10555-1 to demonstrate that the device meets the hub aspiration air leakage requirements.	No air leakage.
Corrosion resistance	The proposed device was evaluated per ISO 10555-1 to demonstrate that the device is corrosion resistant.	Corrosion resistance met acceptance criteria.
Connector performance	The proposed device was evaluated per ISO 594-1, 594-2 and 80369-7 to demonstrate that the device meets the requirements for small bore connectors.	Connector performance met acceptance criteria.
Compatibility test	Simulated use testing with compatible devices in a vascular model was performed.	The device can be used as intended.

Biocompatibility

The device is categorized as Externally Communicating Device, Circulating Blood, Limited Contact (< 24 hours), per ISO 10993-1, the following testing was conducted:

Test	Reference Standard	Test Summary	Conclusion
Cytotoxicity	Tested in accordance with ISO 10993-5:2009, Biological Evaluation of Medical Devices – Part 5: Tests for in vitro toxicity.	Verify the viability, if viability is reduced to < 70% of the blank, it has a cytotoxic potential.	Non-cytotoxic
Irritation	Tested in accordance with ISO 10993-10:2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization.	Study animals tested with the subject device were observed for dermal sensitization.	No irritation

Sensitization	Tested in accordance with ISO 10993-10, Biological Evaluation of Medical Devices – Part 10 Tests for Irritation and Skin Sensitization.	Study animals tested with the subject device were observed for dermal sensitization.	No sensitization
Systemic Toxicity	Tested in accordance with ISO 10993-11:2017, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.	Study animals tested with the subject device were observed for abnormal clinical signs indicative of toxicity during the 72-hour test period.	No systemic toxicity
Hemolysis	Tested in accordance with ASTM F756-17, Standard Practice for Assessment of Hemolytic Properties of Materials.	The difference between the hemolytic indexes of the subject device and the negative control was evaluated.	Non-hemolytic
Material Mediated Pyrogenicity	Tested in accordance with ISO 10993-11:2017, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity and USP 42 <151> Pyrogen Test.	Study animals were observed for temperature rise.	Nonpyrogenic
In Vivo Thromboresistance	Tested in accordance with ISO 10993-4:2017, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood.	Study animals with subject device were observed for thrombogenic potentials and test results demonstrated similar thromboresistance characteristics with the control device.	Met the predetermined acceptance criteria, the test score is 0, i.e., No thrombosis.
Complement Activation	Tested in accordance with ISO 10993-4, Biological Evaluation of Medical Devices – Part 4:2017: Selection of Tests for Interactions with Blood, SC5b-9 Complement Activation.	Comparison of the subject device SC5b-9 value to the predicate device for all exposure times was performed.	No statistical difference from the predicate device

Partial Thromboplastin Time	Tested in accordance with ISO 10993-4:2017, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, and ASTM F2382-2018, Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time.	The clotting time was observed for both the subject device and the predicate.	No statistical difference from the predicate device.
Bacterial Reverse Mutation	Tested in accordance with ISO 10993-3:2014 Biological evaluation of medical devices- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.	The difference between the number of revertant colonies of the subject device and the negative control was evaluated.	No backward mutation in salmonella typhimurium.
In Vitro Mammalian Cell Gene Mutation	Tested in accordance with ISO 10993-3:2014 Biological evaluation of medical devices- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.	The difference between the mutation frequency of the subject device and the negative control was evaluated.	Non-mutagenic to $TK^{+/-}$-3.7.2C Subline of L5178Y cell.

Sterilization and Shelf Life

The Micro Catheter sterilization process using Ethylene Oxide (EO) has been validated in accordance with ISO 11135:2014 to achieve a sterility assurance level (SAL) of 10^{-6}. EO and Ethylene Chlorohydrin (ECH) residuals were below the limits specified in ISO 10993-7:2008. Bacterial Endotoxin Levels were below the level of 2.15 EU/device in accordance with USP <85>. Both baseline and accelerated shelf life testing were conducted demonstrating the device will perform as intended to support the proposed 2 year shelf-life.

9. Clinical Performance Testing

No clinical studies were necessary to demonstrate substantial equivalence.

10. Conclusion

The subject device has similar technological characteristics and intended use as the predicate device. The differences do not raise new questions of safety and effectiveness. The biocompatibility, sterility and bench performance testing demonstrate that the Micro Catheter is substantially equivalent to the predicate device.