August 25, 2021

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

Re: K202916
Trade/Device Name: Balloon Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: July 16, 2021
Received: July 23, 2021

Dear Dinana 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,

Xiaolin Zheng, Ph.D.
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)*
K202916

Device Name
Balloon Guiding Catheter

Indications for Use *(Describe)*
The Balloon Guiding Catheter is intended to assist intravascular catheterization and guidance of an intravascular catheter into a selected vessel in the neuro or peripheral vascular system. The balloon can provide temporary vascular occlusion during angiography.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92. 510(k) Number: K202916

1. Date of Preparation: 08/24/2021

2. Sponsor Identification [807.92(a)(1)]

Shanghai Heartcare Medical Technology Co., Ltd.

590 Ruiqing Rd, Building 4, Suite 201, East Zhangjiang High-Tech Park, Shanghai, P.R. China

Contact Person: Zongyu Xue

Position: Director of Quality Regulations Tel:
+86-18621683501
Fax: +86-21-68798512

Email: zyxue@strokemedical.com

3. Designated Submission Correspondent Ms.

Diana Hong (Primary Contact Person)

Ms. Tingting Su (Alternative Contact Person)

Mid-Link Consulting Co., Ltd

P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,

Fax: 360-925-3199

Email: info@mid-link.net

4. Identification of Proposed Device [807.92(a)(2)]

Trade Name: Balloon Guiding Catheter;
Common Name: Percutaneous Catheter;
Models: SM*BGC-S80; SM*BGC-S95; SM*BGC-S+80; SM*BGC-S+95

Regulatory Information

Primary Product Code: QJP

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

Secondary Product Code: DQY

Classification Name: Percutaneous Catheter
Classification: II
Regulation Number: 21 CFR 870.1250
Review Panel: Cardiovascular

Indications for Use [807.92(a)(5)]

The Balloon Guiding Catheter is intended to assist intravascular catheterization and guidance of an intravascular catheter into a selected vessel in the neuro or peripheral vascular system. The balloon can provide temporary vascular occlusion during angiography.

Device Description [807.92(a)(4)]

The proposed device, Balloon Guiding Catheter, is a braid-reinforced, variable stiffness catheter designed for use in facilitating the guidance of an intravascular catheter into a target vessel in the neuro or peripheral vascular system. A radiopaque marker is included on the distal end for angiographic visualization. A compliant balloon is mounted on the distal end to provide temporary vascular occlusion during angiographic procedures. The proposed device is divided into the S and S+ types with different effective lengths, the difference between S type and S+ type is the size of the catheter.

5. Identification of Predicate Device [807.92(a)(3)]

510(k) Number: K122581

Product Name: Modified Balloon Guide Catheter

6. Predicate Device Comparison [807.92(a)(6)]

The following table provides a comparison of the key characteristics of the Balloon Guiding Catheter to the predicate device.

Table 1 Comparison of Technological Characteristics

ITEM	Proposed Device K202916	Predicate Device K122581	Remark
Device	Balloon Guiding Catheter	Modified Balloon Guide Catheter	
Product Code	QJP, DQY	DQY	Analysis 1
Regulation Number	21 CFR 870.1250	21 CFR 870.1250	Same
Class	II	II	Same
Indications for Use	The Balloon Guiding Catheter is intended to assist intravascular catheterization and guidance of an intravascular catheter into a selected vessel in the neuro or peripheral vascular system. The balloon can provide temporary vascular occlusion during angiography.	The Modified Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.	Analysis 2
Configuration / Components	Balloon	Balloon	Analysis 3
	Outer tube	Outer Jacket	
	Braided tube	Liner	
	Radiopaque ring	Marker Band	
	Tip	Distal Tip	
	Strain Relief tube	Strain Relief	
	Handpiece	Braid	
	Guiding sheath tube	Inner Jacket	
	Guiding sheath fitting	Luer Hub	
	Protective sheath	Peel Away Sheaths	
	Extension tube	Luer-Activated Valve	
	Hemostasis valve Y	Dilator	
	Needleless injection site	Rotating Hemostasis Valve	
	/	Tuohy Borst Valve with side	

			port	
Operation Mode		For manual use only	For manual use only	Same
Sterility		Sterile product	Sterile product	Same
Single Use		Yes	Yes	Same
Catheter	O.D.	SM*BGC-S80: 2.6±0.5mm SM*BGC-S95: 2.6±0.5mm SM*BGC-S+80: 3.0±0.5 mm SM*BGC-S+95: 3.0±0.5 mm	2.7mm (8F)	Analysis 4
	I.D.	SM*BGC-S80: 1.98±0.06mm SM*BGC-S95: 1.98±0.06mm SM*BGC-S+80: 2.25±0.06 mm SM*BGC-S+95: 2.25±0.06mm	2.1mm (6.4F)	
	E.L.	SM*BGC-S80: 80±5 cm SM*BGC-S95: 95±5 cm SM*BGC-S+80: 80±5 cm SM*BGC-S+95: 95±5 cm	100cm and 90cm	
Balloon	Max filling agent volume	0.6 ml	Unknown	Analysis 5
	Max diameter	10±2 mm	Unknown	
	length	9±3 mm	Unknown	
Guiding Sheath	O.D.	1.85±0.06 mm	1.83mm (distal) 1.98mm (proximal)	Analysis 6
	I.D.	0.98±0.06 mm	1.04mm (distal) 1.27mm (proximal)	
	E.L.	115±5 cm 100±15 cm	123cm	
Patient Contacting Materials				
Balloon		Silica gel	Silicone elastomer	Analysis 7
Outer tube		Pebax	Pebax	
Braided tube		Polytetrafluoroethylene (PTFE)	Etched PTFE	
Tip		Pebax and barium sulfate	Pebax and Barium sulfate	
Guiding sheath tube		Pebax and barium sulfate	Pebax and Barium sulfate	
Adhesive		Loctite UV Adhesive and Dymax 204-CTH-T	Loctite UV Adhesive	
Radiopaque Marker		Platinum Alloy	90% Platinum/10% Iridium	
Sterilization				

Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	2.15 EU per device	20 EU per device	Analysis 8

Analysis 1 - Product Code

The proposed device includes an additional product code QJP. The definition of QJP code is "To provide vascular access to the neurovasculature for interventional or diagnostic procedures." The additional product code does not raise new questions of safety and effectiveness.

Analysis 2 - Indications for Use

The indications for use of the proposed device are different from the predicate device. The proposed device does not claim the use of "The product is also indicated for use as a conduit for retrieval devices." Therefore, the difference of the indications for use does not raise new questions of safety and effectiveness.

Analysis 3 - Configuration / Components

There are differences in the set of components of the proposed device and the predicate. This however does not affect the intended use of the device.

Analysis 4 - Catheter specifications

The catheter dimensions for the outer diameter (OD), inner diameter (ID) and effective length (EL) are slightly different compared to the predicate device. However, the dimensional differences do not affect the intended use of the device.

Analysis 5 - Balloon specifications

The physician can control the size of the balloon expansion as necessary. Both devices are intended to provide temporary vascular occlusion during angiographic procedures.

Analysis 6 - Guiding sheath specifications

The guiding sheath dimensions for OD, ID and EL are slightly different compared to the predicate device. However, the dimensional difference does not affect the indications for use.

Analysis 7 - Patient-contacting materials

There are some differences in the patient-contacting materials of the proposed device versus the predicate device. However, the biocompatibility testing for the proposed device has been conducted per ISO 10993 standards. Therefore, the differences do not raise new questions of safety and effectiveness.

Analysis 8-Endotoxin Limit

The proposed device bacterial endotoxin level is below the level of 2.15 EU/device, and the predicate device bacterial endotoxin level is below the level of 20 EU/device. The proposed device has more stringent acceptance criteria for endotoxin levels, and the test results meet the requirements. Therefore, the differences do not raise new questions of safety and effectiveness.

7. Non-Clinical Testing Summary [807.92(b)]

Non-clinical tests were conducted to verify that the proposed device met all design specifications and is Substantially Equivalent (SE) to the predicate device. The test results demonstrate 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"
- ASTM F88/F88M-15 "Standard Test Method for Seal Strength of Flexible Barrier Materials"
- ASTM F1929-15 "Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration"
- ASTM F1886 / F1886M-16 "Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection"
- ASTM F756-17 "Standard Practice for Assessment of Hemolytic Properties of Materials"
- USP <151> Pyrogen Test
- USP <85> Bacterial Endotoxins Test
- 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 a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings"

The results of verification and validation testing conducted on the Balloon Guiding Catheter demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the predicate device. A summary of the tests performed is provided in the table below:

Test	Test Summary	Conclusion
Dimensional verification	Verify dimensions using specified measurement tools. Record measurements.	Size verification 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.
Torque testing	Rotate the catheter in the vascular model to demonstrate that the catheter is capable of rotation without failure.	The catheter body is not damaged and bent.
Balloon compliance	Expand the balloon with varying volumes of expansion liquid and measure the balloon size changes.	Compliant.
Balloon expansion and contraction time	Expand the balloon to the maximum volume, then pull the expansion liquid out, and record the time for expansion and contraction.	Balloon expansion and contraction times met acceptance criteria.

Balloon fatigue test	Repeat expanding and contracting the balloon 20 times to test for balloon leakage or damage.	The balloon is not leaking or damaged
Balloon volume limit	Inject 2.5 times the limit volume of the expansion agent into the balloon and determine if the balloon is damaged.	The balloon is not leaking or damaged.
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.
Catheter bond strength	Use a tensile test machine to apply a tensile load to the bond point and determine if the maximum tensile force meets the acceptance criteria.	Cather bond strength met acceptance criteria.
Compatibility test	Simulated use testing with compatible devices in a vascular model was performed.	The device can be used as intended.
Anti-collapse test	Suction the balloon with maximum suction force to test for increased friction or lumen collapse.	Compatible devices do not experience increased blocking during push and retracement, and the catheter did not collapse.
Burst pressure	Burst pressure tests were performed at pressures greater than the manual syringe injection pressures.	Burst pressure 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.
Air leakage	The proposed device was evaluated per ISO 10555-1 to demonstrate that the product meets the hub aspiration air leakage requirements.	No air leakage
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
Particulate testing	After simulating the use 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 comparator device.
Connector performance	The proposed device was evaluated per ISO 594-1 and 594-2 to demonstrate that the product meets the requirements for small bore connectors.	Connector performance met acceptance criteria.

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.	Meet 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 predicate device

Sterilization and Shelf Life

The Balloon Guiding Catheter sterilization process using Ethylene Oxide (EO) has been validated in accordance with ISO 11135-1:2014 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.

8. Animal Testing

No animal studies were required to demonstrate substantial equivalence.

9. Clinical Test Conclusion

No clinical studies were required to demonstrate substantial equivalence.

10. Conclusion

Shanghai Heartcare Medical Technology Co. Ltd. concludes through a review of the benchtop assessments, the comparison of the device classification, indications for use, technological characteristics, sterility, and biocompatibility testing that the Balloon Guiding Catheter is substantially equivalent to the predicate device.