March 9, 2023

Dongguan TT Medical, Inc.
% Mingzi Hussey
Principal Regulatory Consultant
Zi-medical, Inc.
93 Springs Rd
Bedford, MA 01730

Re: K222663
Trade/Device Name: MultiStage Balloon Dilatation Catheter
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: FGE
Dated: February 10, 2023
Received: February 10, 2023

Dear Mingzi Hussey:

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,

Je An -S

Je Hi An, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology 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)*
K222663

Device Name
MultiStage Balloon Dilatation Catheter

Indications for Use *(Describe)*
The MultiStage Balloon Dilatation Catheters are indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. Also indicated in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy.

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."

Section 5
510(k) Summary
[As required by 21 CFR 807.92]

1. Submission Sponsor

Dongguan TT Medical, Inc.
Address: BLD#1, 1 Taoyuan Road, Songshan Lake, Dongguan, Guangdong, 523808 China
Phone: +86 15553341910
Contact: Yuying Bi, Regulatory Affairs Specialist
Email: ybi @ttmedicalinc.com

2. Submission Correspondent

Mingzi Hussey
Zi-medical, Inc.
Address: 93 Springs Rd, Bedford, MA 01730 US
Phone: 206-981-0675
Email: mingzi@zi-medical.com

3. Date Prepared

Aug 10th, 2022

4. Device Identification

Trade Name: MultiStage Balloon Dilatation Catheter
Regulation name: Biliary Catheter And Accessories
Product Code: FGE
Regulation Number: 21 CFR 876.5010
Regulation Class: Class II
Review Panel: Gastroenterology/Urology

5. Predicate Devices

The proposed device is substantially equivalent to the following predicate device:

Applicant	Device name	510(k) Number	Product code
Boston Scientific Corp	CRE™ Wireguided Balloon Dilatation Catheter	K112994	FGE

6. Device Description

The MultiStage Balloon Dilatation Catheters are indicated for use to endoscopically dilate strictures of the alimentary tract and the Sphincter of Oddi with or without prior sphincterotomy. It consists of an inflatable balloon on a catheter shaft with multiple lumens for inflation and passage of a guidewire.

The MultiStage balloon is designed with three-in-one technology and provides successive, gradual dilation of strictures. The balloon is made of Pebax material. The MultiStage Balloon Dilatation Catheter is designed to pass over a 0.035in (0.89mm) guidewire through its guidewire lumen or through an minimum working channel of a 2.8mm alimentary tract, or a 3.7mm biliary tract. The hub is made of polycarbonate (PC). Two radiopaque tantalum marker bands are positioned within the balloon shoulders to provide visual reference points fluoroscopically for balloon positioning within the stricture. Accordingly, product models, are divided into those with a wireguided (MSW) and non-wireguided (MSO) component.

The MSW model allows the guidewire and catheter to be introduced into the endoscope together. The MSO model as a traditional operation method, the guidewire is first inserted into the endoscope for positioning and then the catheter is inserted through the guidewire for good passability. The physician can choose the model as needed.

7. Indication for Use Statement

The MultiStage Balloon Dilatation Catheters are indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. Also indicated in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy.

8. Comparison of Technological Characteristics

The proposed device is compared with the predicate devices in terms of intended use, technological characteristics and principles of operation. The proposed device shares the similar indications for use, similar materials, same device operation, and same overall technical and functional capabilities as the predicate device. The MSW model has same components with the predicate device while the MSO model does not contain a guidewire for the users to install a guidewire by their choice. The proposed device also has the same standards and requirements as the predicate device, and has been verified for its safety and effectiveness to establish substantially equivalence.

MultiStage Balloon Dilatation Catheter has 72 models:

	Nominal Balloon Diameter					
Nominal Length	6mm	8mm	10mm	12mm	15mm	18mm
30mm	MSO063008	MSO083008	MSO103008	MSO123008	MSO153008	MSO183008
30mm	MSO063017	MSO083017	MSO103017	MSO123017	MSO153017	MSO183017
30mm	MSO063023	MSO083023	MSO103023	MSO123023	MSO153023	MSO183023
55mm	MSO065508	MSO085508	MSO105508	MSO125508	MSO155508	MSO185508
55mm	MSO065517	MSO085517	MSO105517	MSO125517	MSO155517	MSO185517
55mm	MSO065523	MSO085523	MSO105523	MSO125523	MSO155523	MSO185523
30mm	MSW063008	MSW083008	MSW103008	MSW123008	MSW153008	MSW183008
30mm	MSW063017	MSW083017	MSW103017	MSW123017	MSW153017	MSW183017

30mm	MSW063023	MSW083023	MSW103023	MSW123023	MSW153023	MSW183023
55mm	MSW065508	MSW085508	MSW105508	MSW125508	MSW155508	MSW185508
55mm	MSW065517	MSW085517	MSW105517	MSW125517	MSW155517	MSW185517
55mm	MSW065523	MSW085523	MSW105523	MSW125523	MSW155523	MSW185523
MSW: wireguided；MSO: non-wireguided						

9. Description of Non-clinical Testing

The non-clinical tests of the subject device and predicate device are in compliance with the following standards and guidance.

The biocompatibility evaluation for MultiStage Balloon Dilatation Catheter was conducted in accordance with ISO 10993-1.
• Cytotoxicity (ISO 10993-5)
• Sensitization (ISO 10993-10)
• Intracutaneous reactivity test (ISO 10993-10)
Result: All tests were passed.

Shelf life for MultiStage Balloon Dilatation Catheter test is conducted based on ASTM F1980:
• Shelf life test report
Result: All tests were passed.

Sterile barrier systems for MultiStage Balloon Dilatation Catheter were evaluated in accordance with ISO 11607-1:2019.
Sterilization Process has been validated accordance with ISO 11135:2014.
Result: The MultiStage Balloon Dilatation Catheter is sterile with a validation of of the sterilization process that demonstrates achievement of the required SAL of 10^{-6} and is in accordance with the half cycle overkill approach.

Technological characteristics for MultiStage Balloon Dilatation Catheter have been tested for its functions as intended including verification of performance characteristics per performances characteristics relevant to functions as intended:

- Visual Inspection
- Bacteriostasis performance of pouch
- Dye penetration
- Pouch
- Tension test
- Guidewire compatibility test
- Channel compatibility

- Product Dimensional Inspection
- Compliance (deployed balloon dimensional analysis)
- Balloon fatigue; No leakage and damage when inflation
- Balloon rated burst pressure (RBP)
- Peak tensile
- Kink resistance
- Leakage Test
- Hydratability
- Hub
- Corrosion resistance
- X-ray detectability
- Chemical properties

Result: All tests were passed.

The results of Non-Clinical Performance testing demonstrate that the MultiStage Balloon Dilatation Catheter is considered as safe and effective as the predicate.

10. Performance Data-Clinical

No clinical study is included in this submission.

11. Conclusion

The differences in technological characteristics between the proposed device and the predicate device do not raise any different questions of safety or effectiveness. Performance testing and compliance with voluntary standards demonstrate the subject device is substantially equivalent to the relevant aspects of the predicate device in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.

Therefore, the proposed devices are determined to be substantially equivalent to the referenced predicate device.