March 1, 2023

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

Re: K222187
Trade/Device Name: MultiStage Balloon Dilatation Catheter
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: KTI
Dated: February 2, 2023
Received: February 2, 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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K222187

Device Name
MultiStage Balloon Dilatation Catheter

Indications for Use *(Describe)*
MultiStage balloon dilatation catheter is intended to be used to dilate strictures located in the airway tree.

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

[As required by 21 CFR 807.92]

1. Submission Sponsor

Dongguan TT Medical, Inc.
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Contact: Yuying Bi, Regulatory Affairs Specialist
Email: ybi @ttmedicalinc.com

2. Submission Correspondent

Mingzi Hussey
Zi-medical, Inc.
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Phone: 206-981-0675
Email: mingzi@zi-medical.com

3. Date Prepared

May 5th, 2022

4. Device Identification

510(k) Number: K222187
Trade Name: MultiStage Balloon Dilatation Catheter
Common Name/Classification Name: Balloon Dilatation Catheter
Product Code: KTI
Regulation Number: 21 CFR 874.4680
Regulation Class: Class II
Review Panel: Ear Nose & Throat (ENT)

5. Predicate Device

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

Applicant	Device name	510(k) Number	Product code
Boston Scientific Corp	CRE Pulmonary Balloon Dilatation Catheter	K170759	KTI

6. Device Description

The MultiStage Balloon Dilatation Catheter is intended to be used endoscopically to dilate strictures of the airway tree. Balloons designed with three-in-one technology and provides successive, gradual dilation of strictures. The balloon material is made of Pebax material. The MultiStage Balloon Dilatation Catheter

designed to pass over a 0.035in (0.89mm) guidewire through its guidewire lumen or through a minimum 2.8mm working channel bronchoscope. The Catheter 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.

7. Indication for Use

MultiStage balloon dilatation catheter is intended to be used to dilate strictures located in the airway tree.

8. Comparison of Technological Characteristics

The following table compares the proposed device with the predicate device in terms of intended use, technological characteristics and principles of operation, and it provides detailed information for determining substantial equivalences.

General Comparison

ITEM	Proposed Device	Predicate Device	Comments
Trade name	MultiStage Balloon Dilatation Catheter	CRE Pulmonary Balloon Dilatation Catheter	/
510(K) Submitter	Dongguan TT Medical, Inc.	Boston Scientific Corp	/
510(K) Number	K222187	K170759	/
Classification Regulation	21 CFR 874.4680	21 CFR 874.4680	Same
Classification and Product Code	Class II, KTI	Class II, KTI	Same
Common name	Balloon Dilatation Catheter	Balloon Dilatation Catheter	Same
Bronchoscope	Single-Use	Single-Use	Same
Intended Use	MultiStage balloon dilatation catheter is intended to be used to dilate strictures located in the airway tree.	CRE™ Pulmonary Balloon Dilator Catheters is Intended to be used to endoscopically dilate strictures of the airway tree.	MultiStage Balloon Dilatation Catheter and the predicate device are same in terms of indication for use. They are both to be used to dilate strictures located in the airway tree.
Anatomical Locations	Airway tree	Airway tree	Same
Components	1. Tip 2. Balloon 3. Marker Band 4. Inner Tube 5. Outer Tube 6. Strain Relief 7. Hub 8. Protective Sheath 9. Mandrel	1. Tip 2. Balloon 3. Marker Band 4. Inner Tube 5. Outer Tube 6. Stress Relief 7. Hub 8. Protective Sheath 9. Mandrel	Same
Principle of Operation	MultiStage balloon dilatation catheter used to access the airway tree via a bronchoscope	The CRE™ Pulmonary Balloon Dilatation Catheter is used to access the airway tree via a	The only different is the working channel diameter: MultiStage

<table>
<tr><td></td><td>for the purpose of dilating strictures. It is designed to pass over a 0.035in (0.89mm) guidewire through its guidewire lumen or through a minimum 2.8 mm working channel bronchoscope, balloon is capable of 3 distinct and progressively larger size diameters via controlled radial expansion</td><td>bronchoscope for the purpose of dilating strictures. It is designed to pass over a 0.035in（0.89mm） guidewire through its guidewire lumen or through a minimum 5.0 mm working channel bronchoscope, balloon is capable of 3 distinct and progressively larger size diameters via controlled radial expansion</td><td>balloon dilatation catheter has a minimum 2.8mm working channel, which is better than predicate device’s minimum 5.0mm working channel. The difference won’t increase any new safety and efficacy risk.</td></tr>
<tr><td>Marker Band/Location</td><td>Two radiopaque mark are placed under the balloon segment of the catheter to provide visual reference points fluoroscopically for balloon positioning within the stricture.</td><td>Two radiopaque mark are placed under the balloon segment of the catheter to provide visual reference points fluoroscopically for balloon positioning within the stricture.</td><td>Same</td></tr>
<tr><td>How Supplied</td><td>Sterile， Single use only</td><td>Sterile， Single use only</td><td>Same</td></tr>
<tr><td>Sterilization method</td><td>EO</td><td>EO</td><td>Same</td></tr>
<tr><td>Outer shaft diameter</td><td>2.5mm</td><td>2.5mm</td><td>Same</td></tr>
<tr><td>Working length(mm)</td><td>90, 180</td><td>110</td><td>Different Multistage Balloon Dilatation Catheter has two type of working length 90mm and 180mm, while the predicate device only has one working length, which is 110mm.</td></tr>
<tr><td>Guiding wire channel</td><td>0.89mm</td><td>0.89mm</td><td>Same</td></tr>
<tr><td>Inflated Balloon OD</td><td><table><tr><td>Inflated Balloon OD (mm)</td><td>Inflation Pressure (ATM)</td></tr><tr><td>6-7-8</td><td>3-6-10</td></tr><tr><td>8-9-10</td><td>3-5.5-9</td></tr><tr><td>10-11-12</td><td>3-5-8</td></tr><tr><td>12-13.5-15</td><td>3-4.5-8</td></tr><tr><td>15-16.5-18</td><td>3.4.5-7</td></tr><tr><td>18-19-20</td><td>3-4.5-6</td></tr></table></td><td><table><tr><td>Inflated Balloon OD (mm)</td><td>Inflation Pressure (ATM)</td></tr><tr><td>8-9-10</td><td>3-5.5-9</td></tr><tr><td>10-11-12</td><td>3-5-8</td></tr><tr><td>12-13.5-15</td><td>3-4.5-8</td></tr><tr><td>15-16.5-18</td><td>3.4.5-7</td></tr><tr><td>18-19-20</td><td>3-4.5-6</td></tr></table></td><td>Multistage Balloon Dilatation Catheter has more model to select in balloon OD and pressure.</td></tr>
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<table>
<tr><td>Balloon Dilation length</td><td>30mm，55mm</td><td>30mm，55mm</td><td>Same</td></tr>
<tr><td>Inflation pressure</td><td><table><tr><td>Inflated Balloon OD (mm)</td><td>Inflation Pressure （ATM）</td></tr><tr><td>6-7-8</td><td>3-6-10</td></tr><tr><td>8-9-10</td><td>3-5.5-9</td></tr><tr><td>10-11-12</td><td>3-5-8</td></tr><tr><td>12-13.5-15</td><td>3-4.5-8</td></tr><tr><td>15-16.5-18</td><td>3.4.5-7</td></tr><tr><td>18-19-20</td><td>3-4.5-6</td></tr></table></td><td><table><tr><td>Inflated Balloon OD (mm)</td><td>Inflation Pressure （ATM）</td></tr><tr><td>8-9-10</td><td>3-5.5-9</td></tr><tr><td>10-11-12</td><td>3-5-8</td></tr><tr><td>12-13.5-15</td><td>3-4.5-8</td></tr><tr><td>15-16.5-18</td><td>3.4.5-7</td></tr><tr><td>18-19-20</td><td>3-4.5-6</td></tr></table></td><td>Multistage Balloon Dilatation Catheter has more model to select in balloon OD and pressure.</td></tr>
<tr><td>Applicable tunnel</td><td>≥15 Fr （2.8 mm）</td><td>≥15Fr （5.0 mm）</td><td>Different MultiStage balloon dilatation catheter has a minimum 2.8mm working channel, which is better than predicate device’s minimum 5.0mm working channel. The difference won’t increase any new safety and efficacy risk.</td></tr>
<tr><td>Materials</td><td>1. Tip: 100% Pebax
2. Balloon: 100% Pebax
3. Marker band: Tantalum
4. Inner tube: 100% Pebax
5. Outer tube: 99.8%Pebax: 0.2% Blue color additives
6. Strain relief: 99.8% HDPE: 0.2% White color additives
7. Hub: 95% Polycarbonate: 5% Bonding agent（Ethylene propylene UV binder）
8. Protective Sheath: 100% HDPE
9. Mandrel: 100% Polyformaldehyde</td><td>1. Balloon: 100% Pebax
2. Marker band: Platinum iridium</td><td>Similar Compared with predicate device marker band material is different, the marker band does not touch the human body. Differences do not raise new questions of safety and efficacy.</td></tr>
<tr><td>Storage condition and Shipping condition</td><td>Store in a cool, dry, dark place. Rotate inventory so that those catheters are used prior to the expiration date on the package label</td><td>Store in a cool, dry, dark place. Rotate inventory so that those catheters are used prior to the expiration date on the package label</td><td>Same</td></tr>
<tr><td>Packaging</td><td>Sterile single package. The</td><td>Sterile single package. Predicate</td><td>Same</td></tr>
</table>

	product is inserted into the dispenser, and put in sterile pouch, the sterile pouch material: PET12/ SPE-250 (LK) composite film and Tyvek 1073B dialysis paper, finally put into the carton.	Device is inserted into HDPE Die-cut insert card, and put in sterile pouch, the sterile pouch material: PET12/ SPE-250 (LK) composite film and Tyvek 1073B dialysis paper.	
Shelf-life	3	3	Same
Cytotoxicity	Comply with ISO10993-5, no cytotoxicity effect	Comply with ISO10993-5, no cytotoxicity effect	Same
Irritation	Comply with ISO10993-10, not an irritant	Comply with ISO10993-10, not an irritant	Same
Sensitization	Comply with ISO10993-10, not a sensitizer.	Comply with ISO10993-10, not a sensitizer.	Same

MultiStage Balloon Dilatation Catheter has 24 models:

	Nominal Balloon Diameter					
Nominal Length	**6mm**	**8mm**	**10mm**	**12mm**	**15mm**	**18mm**
30mm	MSO063009	MSO083009	MSO103009	MSO123009	MSO153009	MSO183009
30mm	MSO063018	MSO083018	MSO103018	MSO123018	MSO153018	MSO183018
55mm	MSO065509	MSO085509	MSO105509	MSO125509	MSO155509	MSO185509
55mm	MSO065518	MSO085518	MSO105518	MSO125518	MSO155518	MSO185518

The differences between those models have been described in 012_ Device Description in this 510K submission.

The proposed device shares the similar indications for use, same device operation, and overall technical and functional capabilities as the predicate device. It also has the same standards and requirements as the predicate device.

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 determination of lethal rate of the sterilization process to demonstrate achievement of the required SAL of 10^{-6} is in accordance to 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
- Balloon fatigue; No leakage and damage when inflation
- Balloon inflation and deflation time
- Balloon rated burst pressure (RBP)
- Peak tensile
- Leakage Test
- Hydratability
- Hub
- Corrosion resistance
- X-ray detectability
- Torsion test

The results of Non-Clinical Performance testing demonstrate that the MultiStage Balloon Dilatation Catheter is considered safe and effective for its intended use.

10. Performance Data-Clinical

No clinical study is included in this submission.

11. Conclusion

It has been shown in this 510(k) submission that the differences between the proposed device and the predicate device do not raise any questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards demonstrate that the proposed 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 device is determined to be substantially equivalent to the referenced predicate device.