June 29, 2023

Dongguan TT Medical, Inc
Yuying Bi
R&D Director
Bld #1, Rm 501, 502,1 Taoyuan Rd
Songshan Lake,Guangdong
Dongguan, GD 523808
China

Re: K230374
Trade/Device Name: Coronary Dilatation Balloon Catheter (VesPenetrator®), Coronary Dilatation Balloon Catheter (VesTraveler®), Coronary Dilatation Balloon Catheter (VexPander®)
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: February 13, 2023
Received: February 13, 2023

Dear Yuying Bi:

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,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2023.06.29 20:19:00 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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)*
K230374

Device Name
Coronary Dilatation Balloon Catheter (VesPenetrator®);
Coronary Dilatation Balloon Catheter (VesTraveler®);
Coronary Dilatation Balloon Catheter (VexPander®)

Indications for Use *(Describe)*

The VesPenetrator®, VesTraveler® Coronary Dilatation Balloon Catheters are indicated for:
• balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion
• balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction

The VexPander® Coronary Dilatation Balloon Catheters are indicated for:
• balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion
• balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction
• in-stent restenosis
• post-delivery expansion of balloon expandable coronary stents

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

510(k) number: K230374

This 510(k) summary is submitted in according with 21 CFR 807.92.

1. Submitter Information

Submitter's Name:	Dongguan TT Medical, Inc
Submitter's Address:	Bld #1, Rm 501, 502, Taoyuan Rd Songshan Lake, Guangdong Dongguan GD 523808 China
Contact Person:	Yuying Bi
Telephone:	+86-1555334190
Email:	ybi@ttmedicalinc.com
Submission date:	October 10, 2022

2. Subject Device Information

Device Trade Name:	Coronary Dilatation Balloon Catheter (VesPenetrator®); Coronary Dilatation Balloon Catheter (VesTraveler®); Coronary Dilatation Balloon Catheter (VexPander®)
Device Common Name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Classification Name:	Catheters, Transluminal Coronary Angioplasty, Percutaneous
Regulation Number:	21 CFR 870.5100
Product Code:	LOX
Device Class:	Class II
Classification Panel:	Cardiovascular
510(k) Number:	K220279

3. Predicate Device Information

Predicate Device:	Sapphire® NC Coronary Dilatation Catheter (K103808, cleared August 9, 2011)
Reference Device 1:	Mozec ™ NC-Rx PTCA Balloon Dilatation Cather (K160961, cleared July 20, 2016)
Reference Device 2:	Tamarin Blue® PTCA RX Dilatation Cather (K112735, cleared November 2, 2012)
Reference Device 3:	Sapphire® Coronary Dilatation Catheter (K103657, cleared August 9, 2011)

4. Device Description Summary

The Coronary Dilatation Balloon Catheter (VesPenetrator®, VesTraveler® and VexPander®) is a percutaneous transluminal coronary angioplasty (PTCA) is indicated for balloon dilatation of the stenotic portion of a coronary artery. Balloon diameters ranged from 1.5mm to 4.0mm. The balloon is made of Nylon material with a rated burst pressure of 16 atmospheres (atm) for both VesPenetrator and VesTraveler, and 18atm for VexPander. The proximal shaft of the catheter is composed of a female

luer connector bonded to a PTFE coated stainless steel tube. The proximal shaft joins with a smooth transition to a distal shaft composed of an outer tube of nylon or Pebax and a tri-extrusion inner tube with a balloon welded to both tubes at the distal tip. Two radiopaque platinum marker bands are positioned within the balloon shoulders. The inner tube accepts a standard 0.014 inch guidewire. The guide wire enters the catheter's tip and advances coaxially out the distal Rx port, thereby allowing both coaxial guidance and rapid exchange of catheter with a single standard length guide wire. Two marked sections of 5mm length each located on the proximal shaft indicate catheter position relative to the tip of the brachial artery or the guide tube of the femoral artery.

5. Intended Use/ Indications for Use

The VesPenetrator®, VesTraveler® Coronary Dilatation Balloon Catheters are indicated for:

• balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion
• balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction

The VexPander® Coronary Dilatation Balloon Catheters are indicated for:

• balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion
• balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction
• in-stent restenosis
• post-delivery expansion of balloon expandable coronary stents

6. Comparisons with Predicate Device

Comparisons of the subject devices, coronary dilatation balloon catheter (VesPenetrator®, VesTraveler®, VexPander®), and the predicate device, Sapphire® NC plus coronary dilatation catheter shows that the subject device such as indication for use, prescription use and design (such as effective length, guide wire size, proximal shaft diameter, distal shaft diameter, monorail catheter, markers bands, sterilization method) are identical. In the terms of balloon diameter and balloon compliance, VesPenetrator® & VesTraveler® are identical to Sapphire® coronary dilatation catheter, and VexPander® is identical to Sapphire® NC plus coronary dilatation catheter, details are provided in Table 1.

Comparisons of the subject devices to the reference device show that the balloon length of subject device covered by reference device Mozec™ NC-Rx PTCA balloon dilatation catheter, the coating of subject device is identical to reference device Tamarin Blue® PTCA RX dilatation catheter, therefore the balloon length and coating do not raise any new questions of safety or effectiveness. Similar nominal pressure and rated bust pressure will be satisfied with technical requirement in compliance and do not raise any new questions of safety or effectiveness. The biocompatibility of subject device conforms to FDA guidance of biological evaluation of medical devices and do not raise any new questions of safety effectiveness.

7. Performance Data

The subject device, coronary dilatation balloon catheter (VesPenetrator®, VesTraveler®, VexPander®), was subjected to the following applicable testing to assure reliable design and performance under the specified testing parameters and ensure that the design and construction are suitable or its intended use as recommended by the *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (FDA; September 8, 2010):*

The results of these tests provided reasonable assurance that the subject device has been designed and tested to assure conformance to the requirements for its intended use. No new questions of safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate device.

Biocompatibility Testing:

Per ISO 10993-1:2018 and FDA guidance, the following tests were performed to ensure the biocompatibility of the subjective device.

- In vitro cytotoxicity, per ISO 10993-5:2009
- Intracutaneous reactivity, per ISO 10993-10: 2010
- Skin sensitization, per ISO 10993-10: 2021
- Acute systemic toxicity, per ISO 10993-11: 2017
- Hemocompatibility (hemolysis, complement activation (SC5b-9, C3a), coagulation (partial thromboplastin time, prothrombin time), in vivo thromboresistance), per ISO 10993-4:2017
- Material mediated pyrogenicity, per USP General Chapter <151>

Non-clinical Testing/Performance Data:

The following tests were completed and support the coronary dilatation balloon catheter (VesPenetrator®, VesTraveler®, VexPander®)

- Catheter visual inspection
- Catheter dimensional inspection
- Guide wire compatibility test
- Guiding catheter compatibility test
- Haemostasis valve compatibility
- Balloon preparation, deployment and retraction
- Balloon fatigue test
- Balloon rated burst pressure (RBP)
- Balloon compliance
- Balloon inflation and deflation time
- Catheter bond strength
- Tip pull test
- Flexibility and kink test
- Torque strength test
- X-Ray detectability
- Particle contamination test
- Balloon rated burst pressure (RBP; in stent)

- Balloon fatigue (repeat balloon inflations; in stent)
- Bacterial endotoxin testing

8. Conclusion

Based on the indications for use, technological characteristics, and performance testing, the coronary dilatation balloon catheter (VesPenetrator®, VesTraveler®, VexPander®) has been shown to shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate device.