



March 20, 2026

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

Re: K260437

Trade/Device Name: Valvuloplasty Balloon Catheter (ValvuloPro)  
Regulation Number: 21 CFR 870.1255  
Regulation Name: Balloon Aortic Valvuloplasty Catheter  
Regulatory Class: Class II  
Product Code: OZT  
Dated: February 10, 2026  
Received: February 11, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**JULIE B. MACKEL -S**

For

Jennifer Kevit, PhD  
Acting Assistant Director  
DHT2B: Division of Circulatory Support,  
Structural, and Vascular Devices  
OHT2: Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K260437

Device Name  
Valvuloplasty Balloon Catheter (ValvuloPro)

Indications for Use (Describe)

The ValvuloPro Valvuloplasty Balloon Catheter is indicated for balloon aortic vavuloplasty.

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: K260437

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, 1 Taoyuan Road, Songshan Lake National High-Tech Industrial Park.  
Dongguan, Guangdong 523808 CHINA  
Contact Person: Yuying Bi  
Telephone: +86-1555334190  
Email: ybi@ttmedicalinc.com  
Submission date: January 14, 2026

### 2. Subject Device Information

Device Trade Name: ValvuloPro Valvuloplasty Balloon Catheter  
Device Common Name: Percutaneous catheter  
Classification Name: Balloon Aortic Valvuloplasty  
Regulation Number: 21 CFR 870.1255  
Product Code: OZT  
Device Class: Class II  
Classification Panel: Cardiovascular  
510(k) Number: K260437

### 3. Predicate Device Information

The subject device is compared to the predicate device, ValvuloPro Valvuloplasty Balloon Catheter (K240967, cleared July 31, 2024), to demonstrate substantial equivalence.

### 4. Device Description Summary

The ValvuloPro Valvuloplasty Balloon Catheter is intended for use in balloon aortic valvuloplasty procedures. The device consists of an inflatable balloon mounted at the distal end of a coaxial catheter shaft. The catheter has an effective working length of 130 cm.

The proximal end of the catheter is equipped with a Y-shaped hub, comprising one port dedicated to balloon inflation and deflation and a second port designed for guidewire access. Two radiopaque tantalum marker bands are positioned at the proximal and distal shoulders of the balloon, providing fluoroscopic visualization to facilitate accurate balloon placement across the target valvular stenosis.

The balloon catheter is sterilized using ethylene oxide and is intended for single use only.

This Special 510(k) submission is submitted to expand the available balloon size options of the ValvuloPro Valvuloplasty Balloon Catheters. The intended use, design concept, materials, and performance characteristics of the device remain unchanged.

## **5. Intended Use/ Indications for Use**

The ValvuloPro Valvuloplasty Balloon Catheter is indicated for balloon aortic valvuloplasty.

## **6. Comparisons with Predicate Device**

At a high level, the subject device and the predicate device share the same intended use and are based on similar technological characteristics, including:

- Over the wire catheter design
- Balloon compliance characteristics
- Catheter materials
- Effective working length
- Method of sterilization (ethylene oxide)

The subject device differs from the predicate device in the following aspects:

- Balloon size configurations
- Expanded compatibility with standard commercially available guidewires
- Expanded compatibility with standard commercially available introducer sheath sizes

These differences are intended to provide additional size options and do not involve changes to the fundamental device design, operating principle, or user interface, and therefore do not raise new questions of safety or effectiveness.

## **7. Biocompatibility**

The ValvuloPro Valvuloplasty Balloon Catheter is manufactured using the same materials as those used in the legally marketed predicate device (K240967).

These materials have been previously evaluated for biocompatibility in accordance with ISO 10993-1, based on the nature and duration of body contact, and were found acceptable for their intended intravascular use.

No new patient-contacting materials or changes in material formulation, surface characteristics, or manufacturing processes have been introduced in the subject device. Therefore, the previously generated biocompatibility data associated with K240967 are applicable to the subject device, and no additional biocompatibility testing was necessary.

## 8. Performance Data

The subject device, ValvuloPro Valvuloplasty Balloon Catheter, was evaluated through applicable non-clinical bench testing to verify that the device performs as intended and to support a demonstration of substantial equivalence to the predicate device.

The testing was conducted in accordance with the FDA guidance document Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters – Premarket Notification (510(k)) Submissions (April 14, 2023), as well as applicable international standards and internal test methods, as appropriate.

The results of the testing demonstrate that the subject device meets its specified performance requirements and that the addition of new size configurations does not introduce new or increased risks. The non-clinical testing does not raise new questions of safety or effectiveness when compared to the predicate device.

### Non-clinical Testing/Performance Data:

The following bench tests were performed to support the ValvuloPro Valvuloplasty Balloon Catheter:

- Product dimensional inspection
- Guidewire compatibility testing
- Introducer sheath compatibility testing
- Balloon compliance testing
- Balloon leakage testing
- Balloon fatigue testing
- Balloon rated burst pressure (RBP) testing
- Balloon inflation and deflation time testing
- Simulated use testing
- Flexibility and kink resistance testing
- Torque strength testing
- Bond strength testing

In vitro bench testing demonstrated that the ValvuloPro Valvuloplasty Balloon Catheter performed as intended and that the device remains suitable for its intended use.

## 9. Conclusion

Based on a comparison of intended use, technological characteristics, and performance testing, the subject device demonstrates substantial equivalence to the predicate device.