



October 12, 2023

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: K231814

Trade/Device Name: ValvuloPro Valvuloplasty Balloon Catheter  
Regulation Number: 21 CFR 870.1255  
Regulation Name: Balloon Aortic Valvuloplasty Catheter  
Regulatory Class: Class II  
Product Code: OZT  
Dated: August 31, 2023  
Received: August 31, 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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Jennifer Bastijanec -S

for Jaime Raben, PhD  
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

## Indications for Use

510(k) Number (if known)

K231814

Device Name

ValvuloPro Valvuloplasty Balloon Catheter

Indications for Use (Describe)

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

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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."*

## K231814 - 510(k) Summary

### 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. Date Prepared

October 12, 2023

### 3. Device Identification

Trade Name: ValvuloPro® Valvuloplasty Balloon Catheter

Common Name/Classification Name: Balloon aortic valvuloplasty catheter

Regulation Number: 21 CFR 870.1255

Regulation Class: Class II

Review Panel: Cardiovascular

### 4. Predicate Devices

The proposed devices are substantially equivalent to the following predicate devices:

| Applicant                 | Device name              | 510(k) Number | Product code |
|---------------------------|--------------------------|---------------|--------------|
| Edwards Lifesciences, LLC | Edwards Balloon Catheter | K140241       | OZT          |

### 5. Device Description

The ValvuloPro® Valvuloplasty Balloon Catheters are indicated for balloon aortic valvuloplasty. It consists of an inflatable balloon on a catheter shaft with multiple lumens for inflation. The effective length of the catheter is 130cm. The y-connector consists of a balloon inflation port and a guidewire lumen. Two radiopaque tantalum marker bands are positioned within the balloon shoulders to provide visual reference points fluoroscopically for balloon positioning within the stricture. The balloon catheter is supplied sterilized by ethylene oxide (EO) for single use.

### 6. Indication for Use Statement

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

### 7. 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 equivalence.

Table 1 – General Comparison

| # | Items                     | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Predicate Device                                                                                                                                                                                                                                                                                               | Comments |
|---|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| 1 | Trade Name                | ValvuloPro® Valvuloplasty Balloon Catheter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Edwards Transfemoral Balloon Catheter                                                                                                                                                                                                                                                                          | /        |
| 2 | 510 (K) Submitter         | Dongguan TT Medical, Inc.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Edwards Lifesciences, LLC                                                                                                                                                                                                                                                                                      | /        |
| 3 | 510 (K) Number            | /                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | K140241                                                                                                                                                                                                                                                                                                        | /        |
| 3 | Classification Regulation | 21 CFR 870.1255                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 21 CFR 870.1255                                                                                                                                                                                                                                                                                                | Same     |
| 4 | Classification and Code   | Class II, OZT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Class II, OZT                                                                                                                                                                                                                                                                                                  | Same     |
| 5 | Common name               | ValvuloPro® Valvuloplasty Balloon Catheter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Edwards Balloon Catheter                                                                                                                                                                                                                                                                                       | /        |
| 6 | Intended Use              | The ValvuloPro® Valvuloplasty Balloon Catheter is indicated for balloon aortic valvuloplasty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | The Edwards Balloon Catheter is indicated for balloon aortic valvuloplasty.                                                                                                                                                                                                                                    | Same     |
| 7 | Anatomical Locations      | Aortic valve                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Aortic valve                                                                                                                                                                                                                                                                                                   | Same     |
| 8 | Components                | <ol style="list-style-type: none"> <li>1. Tip</li> <li>2. Balloon</li> <li>3. Marker Band</li> <li>4. Inner Tube</li> <li>5. Outer Tube</li> <li>6. Strain Relief</li> <li>7. Hub</li> <li>8. Protective Sheath</li> <li>9. Mandrel</li> </ol>                                                                                                                                                                                                                                                                                                                                           | <ol style="list-style-type: none"> <li>1. Tip</li> <li>2. Balloon</li> <li>3. Marker Band</li> <li>4. Inner Tube</li> <li>5. Outer Tube</li> <li>6. Strain Relief</li> <li>7. Hub</li> <li>8. Protective Sheath</li> <li>9. Mandrel</li> </ol>                                                                 | Same     |
| 9 | Device Description        | The ValvuloPro® Valvuloplasty Balloon Catheters are indicated for balloon aortic valvuloplasty. It consists of an inflatable balloon on a catheter shaft with multiple lumens for inflation. The effective length of the catheter is 130cm. The y-connector consists of a balloon inflation port and a guidewire lumen. Two radiopaque tantalum marker bands are positioned within the balloon shoulders to provide visual reference points fluoroscopically for balloon positioning within the stricture. The balloon catheter is supplied sterilized by ethylene oxide for single use. | The Edwards Transfemoral Balloon Catheter consists of a shaft and balloon with two radiopaque marker bands that indicate the working length of the balloon. The proximal end of the device has a “Y-connector” with a balloon inflation port labeled as “BALLOON” and a guidewire lumen port labeled as “WIRE” | Similar. |

| 10                       | Marker Band/Location           | Two radiopaque tantalum marker bands are positioned within the balloon shoulders.                                                                                                                                                                                             | Two radiopaque marker bands indicate the working length of the balloon. | Same                                                                                                                                                                                         |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
|--------------------------|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|---|----|---|----|---|----|---|----|---|----|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|----|---|----|---|----|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 11                       | How Supplied                   | Sterile, Single use only                                                                                                                                                                                                                                                      | Sterile, Single use only                                                | Same                                                                                                                                                                                         |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 12                       | Sterilization method           | EO                                                                                                                                                                                                                                                                            | EO                                                                      | Same                                                                                                                                                                                         |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 13                       | Working length(cm)             | 130                                                                                                                                                                                                                                                                           | 130                                                                     | Same                                                                                                                                                                                         |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 14                       | Guiding wire channel           | 0.89mm                                                                                                                                                                                                                                                                        | 0.89mm                                                                  | Same                                                                                                                                                                                         |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 15                       | Balloon Minimum Burst Strength | 6atm                                                                                                                                                                                                                                                                          | 6atm                                                                    | Same                                                                                                                                                                                         |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 16                       | Balloon Dilation length        | 40mm                                                                                                                                                                                                                                                                          | 40mm                                                                    | Same                                                                                                                                                                                         |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 17                       | Inflation OD and pressure      | <table><tr><th>Inflated Balloon OD(mm)</th><th>Inflation Pressure (ATM)</th></tr><tr><td>15</td><td>3</td></tr><tr><td>18</td><td>3</td></tr><tr><td>21</td><td>3</td></tr><tr><td>23</td><td>3</td></tr><tr><td>26</td><td>3</td></tr><tr><td>29</td><td>3</td></tr></table> | Inflated Balloon OD(mm)                                                 | Inflation Pressure (ATM)                                                                                                                                                                     | 15 | 3 | 18 | 3 | 21 | 3 | 23 | 3 | 26 | 3 | 29 | 3 | <table><tr><th>Inflated Balloon OD (mm)</th><th>Inflation Pressure (ATM)</th></tr><tr><td>20</td><td>4</td></tr><tr><td>23</td><td>4</td></tr><tr><td>25</td><td>4</td></tr></table> | Inflated Balloon OD (mm) | Inflation Pressure (ATM) | 20 | 4 | 23 | 4 | 25 | 4 | Similar Nominal Pressure (NP) of proposed devices are similar to predicate devices, and satisfied with technical requirement in compliance. Differences do not raise new or different questions regarding safety or effectiveness. |
| Inflated Balloon OD(mm)  | Inflation Pressure (ATM)       |                                                                                                                                                                                                                                                                               |                                                                         |                                                                                                                                                                                              |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 15                       | 3                              |                                                                                                                                                                                                                                                                               |                                                                         |                                                                                                                                                                                              |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 18                       | 3                              |                                                                                                                                                                                                                                                                               |                                                                         |                                                                                                                                                                                              |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 21                       | 3                              |                                                                                                                                                                                                                                                                               |                                                                         |                                                                                                                                                                                              |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 23                       | 3                              |                                                                                                                                                                                                                                                                               |                                                                         |                                                                                                                                                                                              |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 26                       | 3                              |                                                                                                                                                                                                                                                                               |                                                                         |                                                                                                                                                                                              |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 29                       | 3                              |                                                                                                                                                                                                                                                                               |                                                                         |                                                                                                                                                                                              |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| Inflated Balloon OD (mm) | Inflation Pressure (ATM)       |                                                                                                                                                                                                                                                                               |                                                                         |                                                                                                                                                                                              |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 20                       | 4                              |                                                                                                                                                                                                                                                                               |                                                                         |                                                                                                                                                                                              |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 23                       | 4                              |                                                                                                                                                                                                                                                                               |                                                                         |                                                                                                                                                                                              |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 25                       | 4                              |                                                                                                                                                                                                                                                                               |                                                                         |                                                                                                                                                                                              |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |
| 18                       | Applicable tunnel              | 15F(5.0mm)                                                                                                                                                                                                                                                                    | 20×40mm, 23×40mm:<br>14Fr(4.7mm)<br>25×40mm: 16F(5.3mm)                 | Similar Applicable tunnel of proposed device is satisfied with technical requirement in crossability. Differences do not raise new or different questions regarding safety or effectiveness. |    |   |    |   |    |   |    |   |    |   |    |   |                                                                                                                                                                                      |                          |                          |    |   |    |   |    |   |                                                                                                                                                                                                                                    |

|    |                                          |                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                        |
|----|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 19 | Materials                                | <ol style="list-style-type: none"> <li>1. Tip: Pebax</li> <li>2. Balloon: PA 12</li> <li>3. Marker band: Tantalum</li> <li>4. Inner tube: Pebax</li> <li>5. Outer tube: PA12</li> <li>6. Strain relief : PE</li> <li>7. Hub: Polycarbonate</li> <li>8. Protective Sheath: HDPE</li> <li>9. Mandrel: Polyformaldehyde</li> </ol> | <ol style="list-style-type: none"> <li>1. Tip: unknown</li> <li>2. Balloon: Nylon</li> <li>3. Marker band: Platinum / iridium</li> <li>4. Inner tube: Pebax</li> <li>5. Outer tube: Pebax</li> <li>6. Strain relief : unknown</li> <li>7. Hub: Polycarbonate</li> <li>8. Protective Sheath: unknown</li> <li>9. Mandrel: unknown</li> </ol> | <p>Similar</p> <p>The material used in marker bands is different from the predicate device. The adhesives used in the hubs differ. The marker bands and the hub do not have direct contact with the human body. The radiopacity of the Tantalum marker bands is confirmed in testing. Therefore, the differences do not raise new questions of safety or efficacy.</p> |
| 20 | Storage condition and Shipping condition | Store in a cool, dry, dark place. Rotate inventory so that catheters are used prior to the expiration date on the package label                                                                                                                                                                                                 | Store in a cool, dry place.                                                                                                                                                                                                                                                                                                                 | Same                                                                                                                                                                                                                                                                                                                                                                   |
| 21 | Shelf-life                               | 3 years                                                                                                                                                                                                                                                                                                                         | 3 years                                                                                                                                                                                                                                                                                                                                     | Same                                                                                                                                                                                                                                                                                                                                                                   |

ValvuloPro® Valvuloplasty Balloon Catheter has 6 models:

| Balloon Diameter (mm) | Balloon Length<br>40 mm |
|-----------------------|-------------------------|
| 15                    | VBC1540                 |
| 18                    | VBC1840                 |
| 21                    | VBC2140                 |
| 23                    | VBC2340                 |
| 26                    | VBC2640                 |
| 29                    | VBC2940                 |

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

## 8. 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 ValvuloPro® Valvuloplasty Balloon Catheter was conducted in accordance with ISO 10993-1.

- Hemolysis (ISO10993-4)
- Partial Thromboplastin Time (ISO10993-4)
- Prothrombin time (ISO10993-4)
- Thromboresistance (ISO10993-4)
- Acute Systemic Toxicity (ISO 10993-11)
- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Intracutaneous reactivity test (ISO 10993-10)
- Pyrogenicity (ISO10993-11)
- Complement activation (SC5b-9) (ISO10993-4)
- Complement activation (C3a) (ISO10993-4)

Result: All tests were passed.

Sterile barrier systems for ValvuloPro® Valvuloplasty Balloon Catheter were evaluated in accordance with ISO 11607-1:2019.

The ethylene oxide sterilization process has been validated in accordance with ISO 11135:2014.

Result: The ValvuloPro® Valvuloplasty Balloon Catheter is sterile with a determination of lethal rate of the sterilization process to demonstrate achievement of the required SAL of  $10^{-6}$  via half cycle overkill approach.

Technological characteristics for ValvuloPro® Valvuloplasty Balloon Catheter have been tested including verification of performance characteristics relevant to the intended device function. Relevant testing was conducted on samples before and after aging to establish device shelf life.

**Packaging Test:**

- Visual inspection
- Bacteriostasis performance of pouch
- Seal integrity: Dye penetration test
- Seal integrity: Bubble emission test
- Seal strength: Pouch tension test

**Balloon Catheter Testing:**

- Guidewire compatibility test
- Channel compatibility
- Product Dimensional Inspection
- Compliance
- Balloon fatigue; No leakage and damage when inflated
- Balloon rated burst pressure (RBP)
- Simulated use
- Flexibility and kink
- Torque strength
- Peak tensile strength
- Leakage Test
- Hydratability
- Corrosion resistance

- Hub
    - Gauging
    - Stress cracking
    - Liquid leakage
    - Air leakage
    - Separation force
    - Unscrewing torque
    - Easy of assembly
    - Resistance to overriding
  - X-ray detectability
  - Chemical properties
- Result: All tests were passed.

The results of Non-Clinical Performance testing demonstrate that the ValvuloPro® Valvuloplasty Balloon Catheter is substantially equivalent to the predicate.

## **9. Performance Data-Clinical**

No clinical study is included in this submission.

## **10. Conclusion**

The evidence presented in this 510(k) submission demonstrates that the differences between the proposed device and the predicate device do not raise any new questions regarding safety or 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.