March 11, 2025

DISA Medinotec
% Matthew Krueger
Senior Consultant
Biologics Consulting Group
100 Daingerfield Road
Suite 400
Alexandria, Virginia 22314

Re: K241562
Trade/Device Name: OutFlo Aortic Valve Dilatation Balloon Catheter
Regulation Number: 21 CFR 870.1255
Regulation Name: Balloon aortic valvuloplasty catheter
Regulatory Class: Class II
Product Code: OZT
Dated: March 6, 2025
Received: March 6, 2025

Dear Matthew Krueger:

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.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JULIE B. MACKEL -S

For

Rachel Neubrander, PhD
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241562

Device Name
OutFlo Aortic Valve Dilatation Balloon Catheter

Indications for Use *(Describe)*
The OutFlo Aortic Valve Dilatation 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.

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In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 510(k) Summary for the OutFlo Aortic Valve Dilatation Balloon Catheter (OutFlo) is provided below.

1. SUBMITTER

Applicant:	DISA Medinotec Stand 171, Northlands Business Park, Bush Telegraph Street, Northriding, Johannesburg, 2169, South Africa +27 (0) 87 330 2301
Contact:	Lyndon Oldfield Quality & Regulatory Affairs Manager DISA Medinotec +27 (0) 87 330 2301 lyndon@disals.co.za
Submission Correspondent:	Matthew Krueger Senior Consultant Biologics Consulting Group, Inc. 100 Daingerfield Rd., Suite 400 Alexandria, VA 22314 667-352-2578 mkrueger@biologicsconsulting.com
Date Prepared:	March 10, 2025

2. DEVICE

Device Trade Name:	OutFlo
Device Common Name:	OutFlo Aortic Valve Dilatation Balloon Catheter
Classification Name	21 C.F.R. 870.1255, Balloon aortic valvuloplasty catheter
Regulatory Class:	Class II
Product Code:	OZT

3. PREDICATE DEVICE

Predicate Device: K172932 – C. R. Bard True™ Flow Valvuloplasty Perfusion Catheter

4. DEVICE DESCRIPTION

The OutFlo Aortic Valve Dilatation Balloon Catheter (marketing name: OutFlo) is a sterile, single use, Over-the-Wire (OTW) dual-lumen catheter with a hub at the proximal end and a balloon cluster at the distal end.

The proposed device consists of a series of parallel balloons on a catheter which, when deployed, provides an outward radial force while also creating an inter balloon space or passage for blood flow. Thus, buildup of pressure in the ventricle is avoided.

The dilation catheter is intended to be used in conjunction with a 14F or larger guiding catheter and a 0.035" or smaller guidewire, and Y-connectors, none of which are supplied by the manufacturer.

The OutFlo Aortic Valve Dilatation Balloon Catheter is provided in five models. The only difference between the models are the balloon diameter. Refer to Table 1 for the specifications for each of the 5 models.

Table 1: Catheter Models and Balloon Specifications

Product Reference Number	Balloon Length (mm)	Balloon Diameter (mm)	Nominal Pressure (atm)	Maximum Pressure (atm)
OTF1-18040	40	18	8	12
OTF1-20040	40	20	8	12
OTF1-23040	40	23	8	12
OTF1-25040	40	25	8	12
OTF1-28040	40	28	8	12

5. INTENDED USE/INDICATIONS FOR USE

The OutFlo Aortic Valve Dilatation Balloon Catheter is indicated for balloon aortic valvuloplasty.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

Predicate Device Indications for Use
K172932 – C. R. Bard True™ Flow Valvuloplasty Perfusion Catheter

> *The True® Flow Valvuloplasty Perfusion Catheter is indicated for balloon aortic valvuloplasty.*

Subject Device Indications for Use

The OutFlo Aortic Valve Dilatation Balloon Catheter is indicated for balloon aortic valvuloplasty.

The intended use of OutFlo (internal device name: OutFlo Aortic Valve Dilatation Balloon Catheter) is the same as that of the predicate C. R. Bard True™ Flow Valvuloplasty Perfusion Catheter. The proposed Indications for Use statement is identical to the predicate, apart from the actual named device.

Technological Comparisons

The OutFlo Aortic Valve Dilatation Balloon Catheter has the following similarities to the predicate device (C. R. Bard True™ Flow Valvuloplasty Perfusion Catheter [K172932]):

- Same intended use
- Same indications for use
- Same target population
- Same operating principle
- Same fundamental design and technology
- Same sterility assurance level

The minor differences between the subject device and predicate device do not raise questions of safety and effectiveness. Performance testing demonstrates that the subject device performs as intended, meets the device specifications, and thus is substantially equivalent to the predicate device.

7. PERFORMANCE DATA

Biocompatibility Testing

The balloons, inner and outer lumens, and tip tubing components are direct patient contacting devices classified as an externally communicating device, in contact with circulating blood, with limited contact duration (≤24h) based on the intended use. Other parts of the catheter (radiopaque marker, film on the inner surface of the balloon cluster, adhesive, hub, and strain relief) are indirect patient contacting classified as an externally communicating device, in contact with circulating blood, with limited contact duration (≤24h).

The OutFlo Aortic Valve Dilatation Balloon Catheter passed all biocompatibility testing.

Sterilization and Shelf Life

The device is EO sterilized and is validated in accordance with ISO 11135:2014. The sterility assurance level is 10^{-6}. The OutFlo Aortic Valve Dilatation Balloon Catheter has been verified according to ISO 10993-7:2008 “Biological Evaluation of Medical Devices – Part 7: Ethylene

Oxide Sterilization Residuals". Shelf-life testing was conducted to support a 3-year shelf life. Packaging was tested for seal strength and bubble leak.

Bench Testing

The following performance testing demonstrates substantial equivalence to the predicate device and addresses the special controls as stated in 21 CFR 870.1255 (b)(3), that the OutFlo Aortic Valve Dilatation Balloon Catheter performs as intended, and that the catheter meets its device specifications:

- Visual inspection and dimensional verification
- Force to remove balloon protector
- Crossing diameter
- Simulated use
- Friction on guidewire
- Visibility/radiopacity
- Catheter compliance behavior and nominal length measurement
- Inflation and Deflation Times and Fatigue Resistance with no restriction
- Inflation and Deflation Times and Fatigue Resistance with restriction
- Rated Burst Pressure
- Catheter Kink
- Torque Strength
- Pull Testing
- Air Leakage
- Liquid Leakage
- Steady Flow
- Cluster Crush
- Radial Strength
- Tip Perforation
- High Tensile Load Balloon Deflation

Clinical Data

A prospective, multi-center, observational study was conducted on the OutFlo Aortic Valve Dilatation Balloon Catheter for use in the treatment of aortic valve stenosis. The study was intended to evaluate the ability of the OutFlo to be deployed within the aortic valve while allowing blood flow through the inter-balloon space, thus eliminating the need for pacing during the procedure. The study enrolled 40 subjects across five centers. Performance of the device was evaluated by the investigators and subjects were evaluated based on freedom from major adverse events (MAE) and death. Results demonstrated a 98% procedural success rate, no reported deaths, and no reported MAEs related to the device or valvuloplasty procedure. The clinical testing supports substantial equivalence of the device to the predicate and complies with special controls as defined in 21 CFR 870.1255 (b)(4).

8. CONCLUSION

Based on the detailed comparison to the predicate device and the performance testing, the OutFlo Aortic Valve Dilatation Balloon Catheter can be found substantially equivalent to the predicate device.