June 2, 2025

W. L. Gore & Associates, Inc.
Erika Grecco
Regulatory Affairs Associate
1505 N. Fourth Street
Flagstaff, Arizona 86004

Re: K250410
Trade/Device Name: GORE® Tri-Lobe Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 30, 2025
Received: May 1, 2025

Dear Erika Grecco:

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,

Carmen G. Johnson -S

Carmen Gacchina Johnson, 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

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.

Submission Number *(if known)*

K250410

Device Name

GORE® Tri-Lobe Balloon Catheter

Indications for Use *(Describe)*

The GORE® Tri-Lobe Balloon Catheter is intended to assist in the dilatation of self-expanding endoprostheses in large diameter vessels.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

510(k) Submitter

W. L. Gore & Associates, Inc.
1505 N. Fourth Street
Flagstaff, AZ 86004

Regulatory Contact: Erika Grecco

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Date Prepared

May 30, 2025

Device Names/Classification

Device Name: GORE® Tri-Lobe Balloon Catheter

Classification Name: Percutaneous Catheter

Regulation: 21 CFR 870.1250

Classification: Class II

Product Code: DQY

Predicate Devices

K081799, GORE® Tri-Lobe Balloon Catheter

Device Description

The GORE® Tri-Lobe Balloon Catheter is a compliant, tri-lobed polyurethane balloon catheter. The lobed design of the balloon catheter is designed for inflation without complete blockage of aortic blood flow. The three polyurethane balloons are mounted on the leading end of a multi-lumen catheter shaft. Radiopaque markers indicate the balloon edges. Each of the three inflation lumens is in communication with one of the balloons. The inflation port is in communication with all of the inflation lumens and is affixed with a luer lock. The guidewire lumen allows introduction of a 0.035” (0.89 mm) diameter guidewire for over-the-wire access. The trailing end of the guidewire lumen is affixed with a flushing/guidewire port with a luer lock, used for flushing the guidewire lumen. A Tuohy-Borst valve is integrated into the trailing end of the guidewire lumen.

The GORE® Tri-Lobe Balloon Catheter is available in two sizes. The smaller balloon can be inflated to diameters of 16 mm to 32 mm and the larger balloon can be inflated to diameters of 26 mm to 48 mm.

Indications for Use

The GORE® Tri-Lobe Balloon Catheter is intended to assist in the dilatation of self-expanding endoprostheses in large diameter vessels.

The Indication for Use is identical to that of the predicate.

Technological Characteristics

The technological characteristics (materials, design, etc.) compared to the predicate device remain largely unchanged. The only difference, from a technological perspective, between the subject devices and predicate is that the subject devices incorporate changes to the intended balloon diameters and associated recommended inflation volumes, as shown in Table 1 below.

Table. 1 Technological Characteristics between predicate and subject devices

Model Numbers	Predicate Device (K081799) Configuration	Subject Device Configuration
BCM1634/ TBCM1634	Intended Balloon Diameter: 16mm – 32mm Recommended Inflation Volume: 4mL-13mL	Same
BCL2645/ TBCL2645	Intended Balloon Diameter: 26mm – 42mm Recommended Inflation Volume: 12mL-25mL	Intended Balloon Diameter: 26mm – 48mm Recommended Inflation Volume: 12mL-35mL

Summary of Performance Testing

The following testing was conducted to evaluate the changes that are the subject of this submission and demonstrate substantial equivalence to the predicate device:

- Balloon Burst
- Recommended Inflation Volume (RIV) Determination
- Pushability, Trackability, and Kink Resistance
- Torque
- Balloon Inflate / Deflate Time
- Balloon Fatigue
- Simulated Use
    - Aortic Blood Flow
    - Use in the Ascending Aorta
- In Vivo Animal Testing
- Clinical use in the GORE® TAG® Thoracic Branch Endoprosthesis Clinical Trial

In Vivo Animal Testing was completed for the GORE® TAG® Thoracic Branch Endoprosthesis and included validation of the GORE® Tri-Lobe Balloon Catheter in the porcine aortic arch to support the use of the GORE® Tri-Lobe Balloon Catheter in the ascending aorta for the GORE® TAG® Thoracic Branch Endoprosthesis Clinical Trial. The clinical evidence from this study, in combination with the in vitro and in vivo testing, was provided to support the removal of an IFU warning precluding use in the ascending aorta. The data also supported the recommended increased inflation volume and balloon diameters.

Summary of Clinical Data:
The GORE® Tri-Lobe Balloon Catheter was used as an accessory device in the GORE® TAG® Thoracic Branch Endoprosthesis Clinical Trial to assist in the dilatation of the self-expanding GORE® TAG® Thoracic Branch Endoprosthesis. The information that was collected on the use of the GORE® Tri-Lobe Balloon Catheter at the time of the index procedure (Day 0) is summarized below.

The GORE® TAG® Thoracic Branch Endoprosthesis Clinical Trial (G130120) was a prospective, non-randomized, multicenter study evaluating the GORE® TAG® Thoracic Branch Endoprosthesis in the treatment of lesions of the Aortic Arch and Descending Thoracic Aorta (DTA). The data provided specifically in support of this 510(k) focused on the Aortic Arch substudy, though the GORE® Tri-Lobe Balloon Catheter was used also for the DTA substudy.

In G130120, 77 subjects were treated for lesions of the aortic arch; please refer to Table 2 for Baseline Demographic Information. Forty four 44 (57.1%) total subjects had known use of the GORE® Tri-Lobe Balloon Catheter during the index procedure; the balloon was used in the ascending aorta and/or aortic arch in these cases. Those 44 subjects with known GORE® Tri-Lobe Balloon Catheter use experienced zero (0) Day 0 Adverse Events of Aortic Rupture, Aortic Dissection, Balloon Related Mortality, and Type III Endoleak. There was one (1) reported Type I Endoleak at Day 0. The clinical data supports the ability to use the GORE® Tri-Lobe Balloon Catheter in ascending aorta and aortic arch.

Table 2. Baseline Demographic Information

	Aneurysm	Dissection	Other Isolated Lesion	All
Number of Enrolled Subjects	50	24	3	77
Sex				
Male	32 (64.0%)	17 (70.8%)	2 (66.7%)	51 (66.2%)
Female	18 (36.0%)	7 (29.2%)	1 (33.3%)	26 (33.8%)
Ethnicity				
Not Hispanic or Latino	47 (94.0%)	23 (95.8%)	3 (100.0%)	73 (94.8%)
Hispanic or Latino	3 (6.0%)	1 (4.2%)	0 (0%)	4 (5.2%)
Unknown	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Race[1]				
White	27 (54.0%)	14 (58.3%)	3 (100.0%)	44 (57.1%)
Black or African American	6 (12.0%)	6 (25.0%)	0 (0%)	12 (15.6%)
Asian	16 (32.0%)	2 (8.3%)	0 (0%)	18 (23.4%)
American Indian or Alaska Native	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Hawaiian or Pacific Islander	1 (2.0%)	1 (4.2%)	0 (0%)	2 (2.6%)
Other	0 (0%)	2 (8.3%)	0 (0%)	2 (2.6%)
Age (yrs)				
n	50	24	3	77
Mean (Std Dev)	74.3 (8.56)	63.0 (11.31)	73.7 (9.02)	70.8 (10.75)

Median	75.0	63.0	73.0	72.0
Range	(50, 89)	(41, 86)	(65, 83)	(41, 89)
BMI[2]				
n	49	24	3	76
Mean (Std Dev)	27.3 (5.94)	29.9 (4.44)	23.4 (2.01)	27.9 (5.57)
Median	25.6	29.0	24.4	26.9
Range	(16.8, 44.4)	(21.7, 40.2)	(21.1, 24.8)	(16.8, 44.4)
[1]More than one option can be selected.				
[2]Site was queried and the weight for one Subject is unavailable.				

Additional information on the clinical study can be found in the Summary of Safety and Effectiveness for the GORE® TAG® Thoracic Branch Endoprosthesis (P210032/S015).

Conclusion

The GORE® Tri-Lobe Balloon Catheter is substantially equivalent to the predicate device, as supported by the bench, pre-clinical and clinical testing provided. The removal of the warning against use in the ascending aorta, additional larger balloon diameters/recommended inflation volumes, and other minor changes (e.g., addition of new model numbers, burst testing specification) since the last clearance did not raise new concerns related to safety or effectiveness.