October 5, 2018

W.L. Gore and Associates Inc.
Michael Ivey
Regulatory Affairs
1505 N. Fourth St.
Flagstaff, Arizona 86005

Re: K180919
Trade/Device Name: GORE Tri-Lumen Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 4, 2018
Received: September 5, 2018

Dear Michael Ivey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael John -S
2018.10.05 09:40:44 -04'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180919

Device Name
GORE® Tri-Lumen Catheter

Indications for Use *(Describe)*
The GORE® Tri-Lumen Catheter (TLC) is a multi-lumen catheter indicated for use in endovascular procedures requiring multiple guidewires and through-and-through access, in which the catheter leading tip exits the patient, for the implantation of branched stent grafts. Standard techniques for placement of vascular access sheaths, catheters, and wires should be employed.

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) Number: K180919

Device Name: GORE® Tri-Lumen Catheter

Intended Use / Indication for Use:

The GORE® Tri-Lumen Catheter (TLC) is a multi-lumen catheter indicated for use in endovascular procedures requiring multiple guidewires and through-and-through access, in which the catheter leading tip exits the patient, for the implantation of branched stent grafts. Standard techniques for placement of vascular access sheaths, catheters, and wires should be employed.

510(k) Owner:

W. L. Gore & Associates, Inc.
Medical Products Division
1505 North Fourth Street
Flagstaff, Arizona 86004 – U.S.A.

Regulatory Contact:

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Trade or Proprietary Name:	GORE® Tri-Lumen Catheter
Common/Usual/Classification Name:	Catheter, Percutaneous
Product Classification:	Class II
Product Code:	DQY
Regulation Number:	21CFR 870.1250
Classification Panel:	Cardiovascular Devices
Establishment Registration Number:	2017233
Predicate Device:	K072618, Twin-Pass Dual Access Catheter, Vascular Solutions, Inc. (this device has not been the subject of a design-related recall)

Device Description

The GORE® Tri-Lumen Catheter (TLC) is a 140cm long multi-lumen accessory catheter designed to assist with multiple wire introduction and control during endovascular procedures. The central lumen can accommodate one 0.035” guidewire or two 0.018” guidewires while the two auxiliary lumens can each accommodate one 0.018” or 0.014” guidewire. The trailing end of the device has two distinct extension tubes to assist in the introduction of the guidewires into the auxiliary lumens. The leading end of the device is radiopaque to assist in visibility under fluoroscopy. The GORE® Tri-Lumen Catheter is designed to minimize entanglement of multiple guidewires and facilitate through and through access during cardiovascular procedures with fewer snaring maneuvers.

Indications for Use

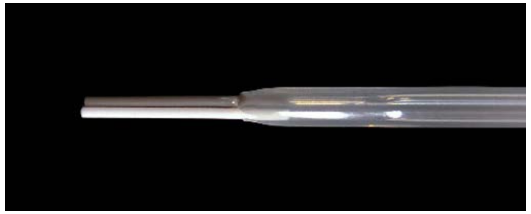
The GORE® Tri-Lumen Catheter (TLC) is a multi-lumen catheter indicated for use in endovascular procedures requiring multiple guidewires and through-and-through access, in which the catheter leading tip exits the patient, for the implantation of branched stent grafts. Standard techniques for placement of vascular access sheaths, catheters, and wires should be employed.

Summary of Similarities and Differences in Technological Characteristics between Applicant and Predicate Devices

A side-by-side comparison of the subject device to the predicate devices is provided in the table below.

Device	GORE® Tri-Lumen Catheter (TLC) (SUBJECT DEVICE)	Twin-Pass Dual Access Catheter (PREDICATE DEVICE)
Manufacturer	W. L. Gore & Associates Inc.	Vascular Solutions, Inc.
510(k) Number	TBD	K072618
Product Code	DQY	DQY
Product Class	II	II
Intended use (Clinical)	Access Peripheral and Aortic Vasculature to Facilitate Guidewire Placement	Access Peripheral, Aortic, and Coronary Vasculature to Facilitate Guidewire Placement
Intended User (Clinical)	Physicians trained in and/or familiar with endovascular procedures and similar devices. This group of physicians may include vascular surgeons, interventional radiologists, and interventional cardiologists from various regions worldwide.	Physicians trained in and/or familiar with endovascular procedures and similar devices. This group of physicians may include vascular surgeons, interventional radiologists, and interventional cardiologists from various regions worldwide.
Operating Principle (Clinical)	The GORE® Tri-Lumen Catheter (TLC) is a multi-lumen catheter designed to minimize entanglement of guidewires while facilitating through and through access during cardiovascular procedures that require the use of multiple guidewires with fewer snaring maneuvers.	The Twin-Pass Dual-Access Catheter is a single use device designed for use in the arterial vasculature to provide support for multiple 0-014"/0.36mm guidewires during interventional procedures.

Device	GORE® Tri-Lumen Catheter (TLC) (SUBJECT DEVICE)	Twin-Pass Dual Access Catheter (PREDICATE DEVICE)
Use Environment (Clinical)	Intended for use in an operating room, catheter lab, or procedural suite which would have bright lighting and ambient sounds. Personal protective equipment, which are typical for the sterile theatre (including gowns, gloves, caps and eye protection) will be used. In addition, the operating room is equipped with fluoroscopy equipment, which requires the user to wear lead apron during use. The device is provided sterile and is intended for one time (single) use. Duration of use is less than 24 hours. Normal disposal via hospital biological waste means.	Intended for use in an operating room, catheter lab, or procedural suite which would have bright lighting and ambient sounds. Personal protective equipment, which are typical for the sterile theatre (including gowns, gloves, caps and eye protection) will be used. In addition, the operating room is equipped with fluoroscopy equipment, which requires the user to wear lead apron during use. The device is provided sterile and is intended for one time (single) use. Duration of use is less than 24 hours. Normal disposal via hospital biological waste means.
Indication for use (Clinical)	Indicated for use in endovascular procedures to facilitate guidewire delivery and management.	Indicated for use in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices during two guidewire procedures.
Catheter Shaft (Technical)	Tri-Lumen Design	Dual-Lumen Design
Guidewire Compatibility (Technical)	Central Lumen: one 0.035” or two 0.018” guidewires Axillary Lumen: one 0.014” or one 0.018” guidewire	Each lumen can accommodate a single 0.014” guidewire
Overall Length (Technical)	140 cm	135 -140 cm
Profile (Technical)	7.5 Fr	3.5 Fr
Catheter Compatibility (Technical)	$\geq$ 12 Fr	$\geq$ 6 Fr

Device	GORE® Tri-Lumen Catheter (TLC) (SUBJECT DEVICE)	Twin-Pass Dual Access Catheter (PREDICATE DEVICE)
Radiopacity (Technical)	Radiopaque Tip	Radiopaque Marker Bands
User Interface (Technical)	Single Central Lumen Tube Dual Axillary Lumen Extension Tubes	Single Port with Separate Rapid Exchange Port
Visual Comparison (Technical)	 Trailing End  Leading End	 Trailing End  Leading End
Materials of Construction (Biological)	Grilamid/Pebax	Pebax / Polycarbonate
Part of body interacted with: (Biological)	Iliac artery, aorta, brachial artery	Iliac artery, aorta, coronary artery
Biocompatibility (Biological)	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1
Sterilization Method (Biological)	Ethylene Oxide	Ethylene Oxide

Performance Data

The GORE® Tri-Lumen Catheter is substantially equivalent to the specified predicate device based on testing of the applicant device functionality, technological characteristics, and indication for use. The device design of the GORE® Tri-Lumen Catheter has been verified by testing to the catheter requirements outlined in BS EN ISO 10555-1:2013 “Intravascular catheters - Sterile and single-use catheters – Part 1: General requirements”. These tests included:

- Guidewire Compatibility
- Catheter Tip Bond Strength
- Radiopacity
- Device Dimensions
- Device Trackability
- Device Pushability
- Device Flushability

Based on the comparisons and information provided in this premarket notification, W.L. Gore & Associates concludes that the GORE® Tri-Lumen Catheter is substantially equivalent to the identified predicate device in terms of indications for use, design, materials, biocompatibility, packaging, sterilization, labeling and performance. The following tests/evaluations were performed to confirm the equivalency, safety, and effectiveness of the device:

- Biocompatibility
- Design Verification
- Design Validation
- Sterilization Validation
- Packaging Integrity
- Product Shelf-Life
- Introducer Sheath compatibility
- Device Torqueability
- Surface Integrity

Animal Data

No Animal Studies were performed as part of this 510(k) Submission.

Clinical Data

No formal clinical study was conducted to specifically evaluate the performance of the GORE® Tri-Lumen Catheter; however, the catheter was used as an accessory device during an Early Feasibility Study to evaluate the initial safety of an investigational aortic stent graft. As part of that early feasibility study, 13 patients were treated with an investigational device that required the use and management of multiple through-and-through guidewires. In each case, a GORE® Tri-Lumen Catheter was used to establish the through-and-through access of the 0.014” and 0.035” guidewires from the brachial artery to the common femoral artery. The GORE® Tri-Lumen Catheter performed this task safely and effectively with no procedural or device related events reported as a result of using the catheter.

Conclusion

W.L. Gore & Associates concludes that the subject GORE® Tri-Lumen Catheter is substantially equivalent to the predicate device.