DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 12, 2016

W.L. Gore & Associates, Inc.
Mary Townsend
Regulatory Affairs Associate
1505 North Fourth Street
Flagstaff, Arizona 86004

Re: K160254
Trade/Device Name: Gore DrySeal Flex Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 8, 2016
Received: April 11, 2016

Dear Mary Townsend:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Brian D. Pullin -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160254

Device Name
GORE® DrySeal Flex Introducer Sheath

Indications for Use *(Describe)*
The GORE® DrySeal Flex Introducer Sheath is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

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
PRAStaff@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."

510(k) SUMMARY
(Per 21CFR807.92)

510(k) Owner:

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

Regulatory Contact:
Mary Townsend
W. L. Gore & Associates, Inc
3450 West Kiltie Lane
Flagstaff, AZ 86001
Phone: 928-864-4192
Fax: 928-864-4304
E-mail: mtownsen@wlgore.com

Date Prepared: January 28, 2016

Device Names/Classification

Trade Name:	GORE® DrySeal Flex Introducer Sheath
510k Number:	K160254
Product Code:	DYB
21CFR	870.1340
Classification Panel*:*	Cardiovascular Devices
Device Class:	Class II

Predicate Devices

K121234 GORE® DrySeal Sheath with hydrophilic coating
K093791 GORE® DrySeal Sheath

Device Description

The GORE® DrySeal Flex Introducer Sheath consists of an introducer sheath with the GORE® DrySeal Valve attached, a twist style locking dilator, and a syringe. The introducer sheath is a composite tube which consists of a flat stainless steel wire reinforced hydrophilic coated Pebax® outer tube and PTFE liner with a tapered leading tip and marker band incorporated within the sheath material to allow identification under fluoroscopy. The sheath is attached to the GORE® DrySeal Valve.

The GORE® DrySeal Valve is comprised of an outer silicone tube and an inner film tube. The region between the silicone tube and film tube is pressurized by injecting 2.5 mL of saline into the space, using the provided syringe, during procedural preparation of the device.

The dilator has a tapered leading end and provides dilatation of the access vessel while providing a smooth transition from the guidewire to the introducer sheath leading tip. The dilator is 0.035" guidewire compatible and has a locking mechanism which mates with, and secures to, the DrySeal Valve. The sheath hub is embossed with its French size and a visual marker on the trailing end of the dilator shaft that ensures correct combination of the dilator within the sheath.

Indications for Use

The GORE® DrySeal Flex Introducer Sheath is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

Summary of Similarities and Difference in Technological Characteristics, Performance and Intended Use

The intended use and indications for the GORE® DrySeal Flex Introducer Sheath device are identical to the predicate GORE® DrySeal Sheath with hydrophilic coating and GORE® DrySeal Sheath. The primary difference between the subject and predicate devices is in the expanded range of French diameters and sheath lengths, the addition of a locking dilator hub to valve mechanism and a coil reinforced, flexible sheath. There are no changes to the hemostatic mechanism of the DrySeal Valve, flush ports, valve fill ports or tubing from the predicate devices.

Performance Data / Predicate Device Comparison

A bench study demonstrated the subject device performed as intended and was substantially equivalent to the predicate devices. The testing included:

Critical Dimensions – IDs and Lengths
Compatibility with Devices-Sheath Dimensions
Guidewire Compatibility
Sheath Tip to Dilator Transition

Radiodetectability
Tortuosity
Kink Resistance
Peak Tensile Force - Critical Junctions
Dilator to Valve Locking Tensile Strength
Dilator Removal Force
System Freedom from Leakage
Lubricity
Particulation
Usability
Shelf life
Biocompatibility Evaluation

Animal study: No animal studies were performed.

Clinical: No clinical evaluations of this product have been conducted.

Conclusion

W.L. Gore & Associates concludes that the subject GORE® DrySeal Flex Introducer is substantially equivalent to the predicate GORE® DrySeal Sheath GORE® DrySeal Sheath with hydrophilic coating and GORE® DrySeal Sheath in terms of indications for use, design, materials, biocompatibility, packaging, sterilization, labeling, and performance.