January 31, 2018

W.L Gore and Associates Inc.  
Jeremiah Andrews  
Regulatory Affairs Associate  
1505 N. Fourth Street  
Flagstaff, Arizona 86004

Re: K172567  
Trade/Device Name: GORE Molding and Occlusion Balloon Catheter  
Regulation Number: 21 CFR 870.4450  
Regulation Name: Vascular Clamp  
Regulatory Class: Class II  
Product Code: MJN  
Dated: December 21, 2017  
Received: December 28, 2017

Dear Jeremiah Andrews:

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.

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.

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,

Nicole G. Ibrahim -S

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

Enclosure
Indications for Use

510(k) Number *(if known)*
K172567

Device Name
GORE Molding and Occlusion Balloon

Indications for Use *(Describe)*
The GORE Molding and Occlusion Balloon Catheter is intended for temporary occlusion of large vessels or to assist in the expansion of self-expanding endovascular prostheses (stent grafts).

Type of Use *(Select one or both, as applicable)*
- [x] 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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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

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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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Phoenix, AZ 85085

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Email: jeandrew@wlgore.com

Date Prepared: January 25, 2018

Device Names/Classification

Trade Name: GORE® Molding and Occlusion Balloon Catheter
Product Code: MJN
21CFR 870.4450
Classification Panel: Cardiovascular Devices
Device Class: Class II

Predicate Devices

<table>
<thead>
<tr>
<th>Device Name</th>
<th>510(k) Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>QXMédical, Q50® PLUS Stent Graft Balloon Catheter</td>
<td>K120381</td>
</tr>
</tbody>
</table>

This predicate device has not been subject to a design-related recall.
**Device Description**

The GORE® Molding and Occlusion Balloon Catheter is a sterile (EtO), single use, single-lobed polyurethane balloon catheter. The compliant polyurethane balloon is mounted on the leading end of a 3 lumen catheter shaft (two inflation lumens and one guidewire lumen). Termination of the leading end of the catheter is an atraumatic catheter leading tip for smooth transition from the guidewire to catheter transition. Radiopaque markers (approximately 40 mm apart) indicate the proximal and distal end of the balloon which aid in proper balloon placement under fluoroscopy. Both of the (2) inflation lumens are in communication with each end of the balloon to facilitate balloon catheter preparation, inflation and deflation. At the trailing end of the balloon catheter is a dual port (balloon inflation and guidewire) y-arm. The inflation port of the y-arm is in communication with both of the balloon inflation lumens and is affixed with a luer lock and three way stopcock via an extension tube. The guidewire lumen of the y-arm 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 luer lock used for flushing the guidewire lumen. The balloon catheter proximal y-arm is provided within a housing which contains markings of the balloon length and inflation range diameter. The balloon can be inflated to diameters of 10 mm to a maximum inflation diameter of 37 mm. The balloon catheter profile is 10 Fr introducer sheath compatible.

**Indications for Use**

The GORE® Molding and Occlusion Balloon Catheter is intended for temporary occlusion of large vessels or to assist in the expansion of self-expanding endovascular prostheses (stent grafts).

**Summary of Similarities and Differences in Technological Characteristics**

Technical Equivalence is established through similar design of single lobed balloon catheter and profile, principal of operation by hydraulic, manual syringe inflation, specification of operating/treatment diameter ranges, fundamental technology and material properties, and user interface.

A comparison of the technical characteristics of the subject and predicate devices is provided in the following table.
## Comparison of the GORE® Molding and Occlusion Balloon Catheter to Predicate Device

*(NOTE: Shaded table cells indicate characteristics that are identical)*

<table>
<thead>
<tr>
<th></th>
<th>GORE® Molding and Occlusion Balloon Catheter</th>
<th>Q50® PLUS Stent Graft Balloon Catheter</th>
<th>Difference Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operating Principal</strong></td>
<td>Device is inserted and withdrawn over a guidewire and through an introducer sheath to the treatment site, via fluoroscopic guidance with the aid of balloon radiopaque marker bands. Device hub allows inflation/deflation of the balloon via a manual syringe.</td>
<td>Device is inserted and withdrawn over a guidewire and through an introducer sheath to the treatment site, via fluoroscopic guidance with the aid of balloon radiopaque marker bands. Device hub allows inflation/deflation of the balloon via a manual syringe.</td>
<td>Subject device does not exceed maximum inflation volume of predicate.</td>
</tr>
<tr>
<td><strong>Max Inflation Volume</strong></td>
<td>48ml</td>
<td>60ml</td>
<td></td>
</tr>
<tr>
<td><strong>Treatment Diameter</strong></td>
<td>10mm – 37mm</td>
<td>10mm – 50mm</td>
<td>Subject device is within the range of treatment diameter of the predicate device.</td>
</tr>
<tr>
<td><strong>Design of Construction</strong></td>
<td>Single-lobed balloon</td>
<td>Single-lobed balloon</td>
<td></td>
</tr>
<tr>
<td><strong>Catheter shaft</strong></td>
<td>3 lumen</td>
<td>3 lumen</td>
<td></td>
</tr>
<tr>
<td><strong>Working Length</strong></td>
<td>90cm</td>
<td>65cm, 100cm</td>
<td>Subject device is within the range of lengths offered for the predicate device.</td>
</tr>
<tr>
<td><strong>Profile</strong></td>
<td>10 Fr</td>
<td>12 Fr</td>
<td>Subject device does not exceed the profile of the predicate device.</td>
</tr>
<tr>
<td><strong>Guidewire Compatibility</strong></td>
<td>0.035”</td>
<td>0.035”</td>
<td></td>
</tr>
<tr>
<td><strong>Radiopacity</strong></td>
<td>Dual balloon marker bands on catheter</td>
<td>Dual balloon marker bands on catheter</td>
<td></td>
</tr>
</tbody>
</table>
| **Balloon diameter versus volume** | 10mm – 2ml  
20mm – 7ml  
30mm – 16ml  
37mm – 35ml | 10mm – 3ml  
20mm – 6ml  
30mm – 16ml  
40mm – 32ml  
50mm – 60ml | Balloon Diameter vs Volume of the devices are similar, but not identical. Predicate device maximum balloon diameter vs volume does not exceed that of the predicate device. |
| **User Interface**       | 2 port y-arm                                | 2 port y-arm                           |                        |
| **Balloon Materials of Construction** | Compliant Polyurethane                   | Compliant Polyurethane                |                        |
| **Catheter Materials of Construction** | Pellethane                                | Pebax                                 | Catheter materials of construction are different. |
| **Sterilization Method** | Ethylene Oxide                             | Ethylene Oxide                        |                        |
Performance Data

Bench study: Design verification testing (listed below) demonstrated the subject device performed as intended and was substantially equivalent to the predicate device.

<table>
<thead>
<tr>
<th>Design Verification Testing</th>
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</thead>
<tbody>
<tr>
<td>Device Profile / Sheath Compatibility</td>
</tr>
<tr>
<td>Guidewire Compatibility</td>
</tr>
<tr>
<td>Repeat Inflation / Deflation</td>
</tr>
<tr>
<td>Balloon &amp; Marker Band Position &amp; Length</td>
</tr>
<tr>
<td>Inflation Time</td>
</tr>
<tr>
<td>Catheter Effective Length</td>
</tr>
<tr>
<td>Deflation Time</td>
</tr>
<tr>
<td>Visual Inspection Mechanical Defects</td>
</tr>
<tr>
<td>Occlusion</td>
</tr>
<tr>
<td>Tip Durability</td>
</tr>
<tr>
<td>Balloon Inflation Diameter</td>
</tr>
<tr>
<td>Tensile Strength</td>
</tr>
<tr>
<td>Burst Volume</td>
</tr>
<tr>
<td>Shelf Life Testing</td>
</tr>
<tr>
<td>Leakage</td>
</tr>
<tr>
<td>Packaging Validation Testing</td>
</tr>
<tr>
<td>Aspiration</td>
</tr>
<tr>
<td>Sterilization Validation Testing</td>
</tr>
<tr>
<td>Accessory Compatibility</td>
</tr>
<tr>
<td>Biocompatibility</td>
</tr>
</tbody>
</table>

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® Molding and Occlusion Balloon Catheter is substantially equivalent to the predicate device.