K103500

MAY 2 3 2011

510(k) SUMMARY [21 CFR 807.92(a)(1)]

1. 510(k) Owner's Contact Information: name, address, phone and fax numbers, name of contact person, and date the summary was prepared [807.92(a)(1)]

Applicant: W. L. Gore & Associates, Inc.
4250 W. Kiltie Lane
Flagstaff, AZ 86001

Contact: Michelle Ann Wells, RAC
Regulatory Affairs
Toll Free: (800) 437-8181
Facsimile: (928) 864-4957
mwells@wlgore.com

Date Prepared: May 19,2011

2. Name of the Device: including the trade or proprietary name, if applicable, the common or usual name, and the classification name, if known [807.92(a)(2)]

- Trade name – GORE® Embolic Filter
- Common name – Percutaneous catheter
- Classification name – Temporary carotid catheter for embolic capture
- Classification – 21CFR 870.1250, NTE Class II

3. Device Predicates [807.92(a)(3)]

K063204 SpiderFX Embolic Protection Device, ev3
K042218 Accunet Embolic Protection System, Abbott

4. Description of the Device [807.92(a)(4)]

The GORE® Embolic Filter system consists of a device, a delivery catheter, and a retrieval catheter, and is compatible with guiding catheters and sheaths having a minimum inner diameter of 0.066". The GORE® Embolic Filter is indicated for general use as a guidewire and embolic protection system during angioplasty and stenting procedures in carotid arteries with reference vessel diameters of 2.5 to 5.5mm.

5. Intended Use [807.92(a)(4)]

The GORE® Embolic Filter system is indicated for general use as a guidewire and embolic protection system during angioplasty and stenting procedures in carotid arteries with reference vessel diameters of 2.5 to 5.5mm.

510(k) SUMMARY [21 CFR 807.92(a)(1)]

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

   The GORE® Embolic Filter is substantially equivalent to the currently marketed devices in intended use, materials, technological characteristics and performance.

7. Performance Data / Predicate Device Comparison [807.92(a)(6)]

   Biocompatibility: Biocompatibility testing of the GORE® Embolic Filter consisted of cytotoxicity, endotoxin, heavy metals, sensitization, irritation, acute systemic toxicity (systemic injection and material mediated), and hemocompatibility (indirect contact and complement activation).

   Non-Clinical: Testing of the GORE® Embolic Filter consisted of biocompatibility, sterilization, packaging, product shelf life and performance testing. These tests demonstrated that the technological characteristics such as product performance, design and intended use are substantially equivalent to the currently marketed predicate devices and include the following:

   System Tests
   - Loading, Deployment and Retrieval Forces
   - Deployment Reliability
   - Radial Force
   - Quantification of Particulate
   - Deployment Cycles
   - Track Force
   - Dimensional Verification
   - Radiopacity Evaluation
   - Critical Landing Zone
   - Lesion Crossing Capability and Force
   - Stent Compatibility
   - Deployment Force in Tortuous Anatomies

   Guidewire Component Tests
   - Tip Flexibility
   - Tensile
   - Torque Response
   - Torque Strength
   - Dimensional

510(k) SUMMARY [21 CFR 807.92(a)(1)]

Filter Component Tests

- Tensile
- Filter Bag Volume
- Filter Efficiency
- Heparin Concentration, Hydrophilicity, Residuals and Elution
- Filter Bag/Pore Size Spacing and Geometry
- Pulsatile Fatigue
- Delivery and Retrieval Catheter Component Testing
- Tensile (Delivery and Retrieval)
- Compressive (Delivery and Retrieval)
- Dimensional (Delivery and Retrieval)

Animal: Animal studies were conducted to evaluate the performance, ease of use, handling characteristics, and vessel damage in tortuous anatomy in accordance with 21 CFR 58.

Clinical: The Gore EMBOLDEN Clinical Trial was a prospective, multicenter, nonrandomized, single-arm study designed to compare 30-day safety and efficacy of the GORE® Embolic Filter System used with FDA approved carotid stents to a performance goal obtained from carotid stent studies utilizing distal embolic protection. Thirty five (35) US sites enrolled 250 pivotal subjects. Statistical analysis confirms that the GORE® Embolic Filter met the performance goal defined for the study, demonstrating the safety and efficacy of the GORE® Embolic Filter for use in carotid artery stenting when used in accordance with the Instructions for Use.

8. Conclusion

The GORE® Embolic Filter is substantially equivalent to the predicate devices in terms of material composition, design, intended use, and performance attributes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

W.L. Gore & Associates, Inc.
c/o Ms. Michelle Wells
4250 W. Kiltie Lane
Flagstaff, AZ 86001

MAY 23 2011

Re: K103500
Trade/Device Name: GORE Embolic Filter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: May 17, 2011
Received: May 18, 2011

Dear Ms. Wells:

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. However, we remind you 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

4 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K103500

Device Name: GORE® Embolic Filter

Indications for Use:

The GORE® Embolic Filter system is indicated for general use as a guidewire and embolic protection system during angioplasty and stenting procedures in carotid arteries with reference vessel diameters of 2.5 to 5.5mm.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K103500