K083300

FEB - 4 2009

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

1. 510(k) Owners 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
W. L. Gore & Associates, Inc.
Medical Products Division
P.O. Box 2400
Flagstaff AZ 86003-2400

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mwells@wlgore.com

Date Prepared: November 7, 2008

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 Flow Reversal System
- Common name – Occlusion catheter
- Classification name – Catheter, carotid, temporary, for embolization capture
- Classification – 21CFR 870.1250, NTE Class II

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

K021210 Arteria Occlusion Balloon

K021293 Arteria Blood Filter

K070770 GORE Balloon Sheath

K072990 Guardwire Temporary Occlusion and Aspiration System

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

The GORE Flow Reversal System consists of three primary components:

- GORE Balloon Sheath
- GORE Balloon Wire, and

- GORE External Filter

When assembled together, the GORE Flow Reversal System reverses the flow of blood at the treatment site of the internal carotid artery (ICA), directing embolic particles away from the neurovascular circulation and removing them through an external filter.

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

The GORE Flow Reversal System is intended to provide embolic protection during carotid artery angioplasty and stenting for the patients diagnosed with carotid artery stenosis and who have the appropriate anatomy described below:

- Adequate iliac/femoral access
- Common carotid artery diameters between 6 and 12 mm
- External carotid artery diameters less than 6 mm

6. Predicate Device Comparison [807.92(a)(6)]

Non-Clinical: Testing of the GORE Flow Reversal System 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.

Clinical: The Gore EMPiRE Clinical Trial was a prospective, multicenter, non-randomized, single-arm study designed to compare 30-day safety and efficacy of the GORE Flow Reversal System used with FDA-approved carotid stents to an objective performance criteria (OPC) determined from prior carotid artery stenting studies where distal embolic protection devices were used. Twenty-nine (29) US sites participated in the study and enrolled 245 pivotal subjects. Statistical analysis confirms that the GORE Flow Reversal System met the OPC hypothesis defined for the study, demonstrating the safety and efficacy of the GORE Flow Reversal System for use in carotid artery stenting when used in accordance with the Instructions for Use.

Conclusion: The GORE Flow Reversal System 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
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2009

W.L. Gore and Associates, Inc.
c/o Ms. Michelle Ann Wells, RAC
Regulatory Affairs
4250 West Kiltie Lane
Flagstaff, AZ 86001

Re: K083300
Trade/Device Name: Gore Flow Reversal System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: January 14, 2009
Received: January 15, 2009

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vickers

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): ~~To be assigned~~ K083300

Device Name: GORE Flow Reversal System

Indications for Use:

The GORE Flow Reversal System is intended to provide embolic protection during carotid artery angioplasty and stenting for the patients diagnosed with carotid artery stenosis and who have the appropriate anatomy described below:

- Adequate iliac/femoral access
- Common carotid artery diameters between 6 and 12 mm
- External carotid artery diameters less than 6 mm

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kochner
(Division Sign-Off)
Division of Cardiovascular Devices

510(K) Number K083300