W. L. GORE & ASSOCIATES, INC.

Creative Technologies Worldwide

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FAX: 520/527-0584

K964067

JUN - 5 1997

PREMARKET NOTIFICATION SUMMARY

1. **Applicant :** W. L. Gore and Associates, Inc.
1505 N. Fourth Street
P.O. Box 3000
Flagstaff, Arizona 86003-3000

2. **Applicant Device :** GORE Irrigation System

Common Name : Irrigation system

Classification Name : Intravascular administration set

3. **Predicate Device :**

For the purposes of demonstrating the premarket clearance of other, similarly-classified, devices, GORE cited FDA-issued 510k's.

4. **Applicant Device Description :**

The GORE irrigation system is composed of biocompatible plastics consistent with those used in other commercially available irrigation systems and intravascular administration sets. All tissue and fluid-path materials will be documented as suitable for intended use per international standards and FDA guidances, prior to commercial distribution and clinical use.

The GORE irrigation system consists of a valve controller, tubing with introducer sheaths, and connections for infusion and drainage of irrigant solution into and from the clamped vein. As the same types of biocompatible plastics used in other irrigation sets will be used in the GORE irrigation set, and all materials used in the GORE irrigation set will be appropriately characterized and tested for biocompatibility, no new issues regarding materials are raised by the GORE device. As the GORE irrigation set operates in a manner similar to other commercially available irrigation sets, and surgical users are very familiar with the use of irrigation sets during vein preparation for in-situ bypass, there are no new issues regarding the technological characteristics or use of the GORE device.

5. **Intended Use :** Like other commercially available vascular irrigation sets and intravascular administration sets, the GORE irrigation system is intended to irrigate vascular tissue intraoperatively. This includes use for infusion of sterile irrigant solution into a vein to allow visualization of pertinent intravascular structures, venous valves and tributary sites, during vein preparation for in-situ vascular bypass.

6. **Technological Characteristics :**

As the GORE irrigation set is structured similarly and operates in a manner similar to other commercially available irrigation sets, and surgical users are very familiar with the use of irrigation sets during vein preparation for in-situ bypass, there are no new issues regarding the technological characteristics or use of the GORE device.

For the past two decades, GORE-TEX Medical Products have been used in more than 4,000,000 clinical applications for a broad range of indications. This extensive clinical history demonstrates that GORE is capable of ensuring that its devices possess the requisite structural, biocompatibility and mechanical characteristics to function safely and effectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Dawn Lopez
Regulatory Affairs
Associate
W.L. Gore & Associate, Inc.
Medical Products Division
3750 West Kiltie Lane
P.O. Box 900
Flagstaff, Arizona 86002-0900

JUN - 5 1997

Re: K964067
GORE Irrigation Set
Regulatory Class: II (Two)
Product Code: 79 FPA
Dated: March 6, 1997
Received: March 7, 1997

Dear Ms. Lopez:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address"dsmo@fdadr.cdrh.fda.gov."

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

800.5440 Intravascular Irrigation Set
FPA II

INDICATIONS FOR USE

510k Number (if known): K964067

Device Name: Gore Irrigation System

Indications for Use:

Like other, commercially available vascular irrigation sets and intravascular administration sets, the GORE irrigation system is intended to irrigate vascular tissue intraoperatively.

This includes use of the GORE irrigation system to infuse sterile irrigant solution into a vein to allow visualization of the valve destruction process during vein preparation for in-situ vascular bypass.

Concurrence of CDRH, Office of Device Evaluation (ODE):

Kate R. Campbell

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K964067

Prescription Use: X OR Over the Counter Use: ____
(per 21 CFR 801.109)

(Optional Format 1-2-96)