K033670

MAY - 5 2004

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Proprietary Name:	GORE Tri-Lobe Balloon Catheter
Common Name:	balloon catheter
Classification Name:	catheter, angioplasty, peripheral, transluminal, percutaneous catheter
Device Classification:	Class II
Product Classification and Code:	870.1250, DQY
Classification Panel:	Cardiovascular Devices
Establishment Registration Number:	2025240
Contact Person:	Brandon Hansen Regulatory Affairs Medical Products Division WL Gore & Associates, Inc. 3450 West Kiltie Lane Flagstaff, AZ 86002-0500 Telephone: (928) 864-3784 Facsimile: (928) 864-4144 E-mail: bhansen@wlgore.com

Performance Standards

Performance standards do not currently exist for these devices. None established under Section 514.

Device Description

The GORE Tri-Lobe Balloon Catheter is a dual lumen catheter with a low pressure compliant balloon attached to the distal end of the catheter. The balloon is a tri-lobe design to allow for limited blood flow when used to touch up an endoprosthesis. The catheter is designed to be used with a 0.035" guidewire. Two 304 stainless steel markers provide angiographic visualization of the balloon length and facilitate intravascular placement of the balloon prior to inflation. The GORE Tri-Lobe Balloon Catheter is provided sterile for single-use.

Indication for Use

The Tri-Lobe Balloon Catheter is intended to assist in the dilatation of self-expanding endoprostheses in large diameter vessels.

Substantially Equivalent Devices

In W. L. Gore & Associates Inc.'s opinion, the GORE Tri-Lobe Balloon Catheter is believed to be substantially equivalent to the following predicate devices currently in interstate commerce with respect to comparable features, materials of construction and intended use.

- ANCURE® Iliac Balloon Catheter (Guidant Cardiac & Vascular Surgery (C&VS), Menlo Park, CA) – K003495
- Equalizer™ Balloon Catheter (Boston Scientific Corporation, Natick, MA) – K021721
- LDOB Occlusion Balloon Catheter (COOK INCORPORATED, Bloomington, IN) – K002286

Labeling, packaging and sterilization of the GORE Tri-Lobe Balloon Catheter is substantially equivalent to that of the predicate devices listed above.

Summary of Studies

W. L. Gore & Associates, Inc. performed device integrity testing to support that the GORE Tri-Lobe Balloon Catheter will perform adequately when used according to the intended use. All device integrity test results for the GORE Tri-Lobe Balloon Catheter met specified requirements.

Conclusion (Statement of Equivalence)

Through data and information presented, numerous similarities support a determination of substantial equivalence, and therefore market clearance of the W. L. Gore & Associates, Inc.'s GORE Tri-Lobe Balloon Catheter through this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2004

W. L. Gore and Associates, Inc.
c/o Mr. Brandon Hansen
Regulatory Affairs
3450 West Kiltie Lane
Flagstaff, AZ 86001

Re: K033670
Trade Name: Tri-Lobe Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 21, 2003
Received: November 24, 2003

Dear Mr. Hansen:

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 Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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): K033670

Device Name: GORE Tri-Lobe Balloon Catheter

Indications For Use:

The Tri-Lobe Balloon Catheter is intended to assist in the dilatation of self-expanding endoprostheses in large diameter vessels.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K033670