K032073

AUG 13 2003

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Proprietary Name:	GORE Introducer Sheath with Silicone Pinch Valve
Common Name:	Introducer Sheath
Classification Name:	Introducer, Catheter
Device Classification:	Class II
Product Classification and Code:	870.1340, DYB
Classification Panel:	Cardiovascular Devices
Establishment Registration Number:	2025240
Contact Person:	Brandon Hansen Regulatory Affairs Medical Products Division W. L. 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 Introducer Sheath with Silicone Pinch Valve is an introducer sheath comprised of a sheath with an attached valve system, hemostasis caps and a dilator. The tip of the dilator is tapered to facilitate atraumatic insertion of the sheath. The valve system helps maintain hemostasis during endovascular procedures. The hemostasis caps contain various size holes that allow for various size devices to be introduced while maintaining hemostasis. The GORE Introducer Sheath with Silicone Pinch Valve is supplied as a sterile, single use device.

Indication for Use

GORE Introducer Sheath with Silicone Pinch Valve is intended to be inserted in the peripheral vasculature to provide a conduit for the insertion of endovascular devices.

Substantially Equivalent Devices

In W. L. Gore & Associates, Inc.'s opinion, the GORE Introducer Sheath with Silicone Pinch Valve is believed to be substantially equivalent to the predicate devices currently in interstate commerce with respect to comparable features, the intended use and the mode of use.

Summary of Studies

W. L. Gore & Associates, Inc. performed device integrity testing on the GORE Introducer Sheath with Silicone Pinch Valve. All device integrity test results for the GORE Introducer Sheath with Silicone Pinch Valve 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 GORE Introducer Sheath with Silicone Pinch Valve through this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2003

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

Re: K032073
Gore TAG Introducer Sheath with Silicone Pinch Valve
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: July 2, 2003
Received: July 3, 2003

Dear Mr. Hansen:

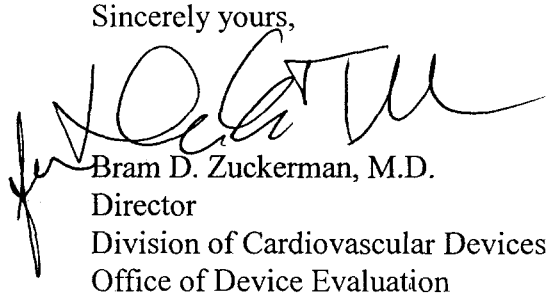
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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

INDICATION FOR USE

510(k) Number (if known): K032073

Device Name: GORE Introducer Sheath with Silicone Pinch Valve

Intended Use / Indication For Use: Intended to be inserted in the peripheral vasculature to provide a conduit for the insertion of endovascular devices

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

X

Prescription Use OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032073