K013648

JAN 0 8 2002

XI. Summary of Safety and Effectiveness

Applicant:

W.L. Gore & Associates, Inc.
3450 West. Kiltie Lane
P.O. Box 500
Flagstaff, AZ 86002-0500

Contact

Timothy J. Rynn

Date Prepared

November 1, 2001

Trade or Proprietary Name

VIABAHN™ Endoprosthesis

Common or Usual Name

Tracheal Endoprosthesis

Classification Name

Tracheal Prosthesis

Device Predicates

Ultraflex™ Tracheobronchial Stent System, WALLSTENT® Tracheobronchial Endoprosthesis, aSpire Covered Stent and Delivery Catheter

Device Description

The *VIABAHN*™ Endoprosthesis is a self-expanding implantable endoprosthesis that is compressed and secured on the distal end of a catheter delivery system. The catheter delivery system provides a means for implanting the endoprosthesis at a target location

K013648

Device Description (cont'd)

within the tracheobronchial tract. The endoprosthesis consists of a fluoropolymeric tube with a nitinol structure located over its external surface. The catheter delivery system is configured with radiopaque markers and is designed for use with guidewires.

Statement of Intended Use

The *VIABAHN*™ Endoprosthesis is indicated for the treatment of tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.

Substantial Equivalence

A variety of tests, assessments, and comparisons demonstrate that the *VIABAHN*™ Endoprosthesis is substantially equivalent to the cited predicates in terms of 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

JAN 0 8 2002

Mr. Timothy J. Rynn
Regulatory Affairs
W. L. Gore & Associates, Inc.
3450 West Kiltie Lane
Flagstaff, Arizona 86001

Re: K013648
Trade/Device Name: VIABAHN™ Endoprosthesis
Regulation Number: 878.3720
Regulation Name: Tracheal prosthesis
Regulatory Class: II
Product Code: JCT
Dated: November 2, 2001
Received: November 5, 2001

Dear Mr. Rynn:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Neil R.P. Ogden for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

XIII. Indications for Use

510(k) Number (if known) K013648

Device Name: *VIABAHN*™ Endoprosthesis

INDICATIONS FOR USE:

The *VIABAHN*™ Endoprosthesis is indicated for the treatment of tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

NRo for cmw

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013648

Prescription Use X **OR** **Over-The-Counter Use** ___
(per 21 CFR 801.109)

(Optional Format 1-2-96)