

4/8/99

K984526

**Tab 8**

**Summary of Safety and Effectiveness**

**Page 1 of 2**

**Applicant:**

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

**Contact**

Timothy J. Rynn

**Date Prepared**

December 11, 1998

**Trade or Proprietary Name**

*ACUSEAL™* Cardiovascular Patch

**Common or Usual Name**

Cardiovascular Patch

**Classification Name**

Intracardiac patch or pledget made of polyethylene, polyethylene terephthalate, or polytetrafluoroethylene (21 CFR § 870.3470).

**Device Predicates**

GORE-TEX® Cardiovascular Patch (K811841 and K912107); CVPro™ Cardiovascular Patch (K943736).

**Device Description**

The *ACUSEAL™* Cardiovascular Patch is an ePTFE cardiovascular patch with an optional manufacturing modification consisting of an additional interpositional layer or layers of a fluoropolymer material. The additional material is intended to reduce suture hole bleeding through suture holes when stured into place using standard surgical techniques.

**Statement of Intended Use**

Intended for use in cardiovascular patching; reduces bleeding through suture holes.

**Substantial Equivalence**

The applicant device is substantially equivalent in materials to currently marketed ePTFE cardiovascular patch devices. Mechanical testing data demonstrate the applicant device has strength values which are substantially equivalent to the predicate devices. *In vivo* testing demonstrates that the reduced bleeding feature of the applicant device does not adversely affect its material characteristics or its tissue response properties.

The applicant device is composed of the same inert ePTFE biomaterial as the GORE-TEX® Cardiovascular Patch, plus an additional interpositional layer of a copolymer material.

No new types of safety and effectiveness issues are raised by the modification of product design or materials to reduce suture hole bleeding.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 8 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Timothy J. Rynn  
Regulatory Associate  
Medical Products Division  
W.L. Gore & Associates, Inc.  
3450 West Kiltie Lane  
P.O. Box 500  
Flagstaff, AZ 86002-0500

Re: K984526  
Acuseal™ Cardiovascular Patch  
Regulatory Class: II (Two)  
Product Code: DXZ  
Dated: March 22, 1999  
Received: March 26, 1999

Dear Mr. Rynn:

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 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). 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. Be advised that all promotional materials must also contain the warning regarding lack of clinical data to assess enhanced ingrowth and associated adverse effects.

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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

Page 2 - Mr. Timothy J. Rynn

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" (21CFR 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 "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

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

510(k) NUMBER (IF KNOWN): K984526

DEVICE NAME: ACUSEAL<sup>TM</sup> Cardiovascular Patch

INDICATIONS FOR USE:

The ACUSEAL<sup>TM</sup> Cardiovascular Patch is indicated for use in cardiovascular patching.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use                        
(Per 21 CFR 801.109)

OR Over-The-Counter-Use                       
(Optional Format 1-2-96)

*Ben L. Dwyer*  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K984526