



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2009

W.L. Gore & Associates, Inc.
c/o Mr. R. Larry Pratt
Regulatory Affairs
3450 West Kiltie Lane
Box 500 -P.O.
Flagstaff, AZ 86002-0500

Re: K960532
GORE PRECLUDE® IMA Sleeve
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac patch or pledget
Regulatory Class: II (two)
Product Code: MFX
Dated: February 5, 1996
Received: February 7, 1996

Dear Mr. Pratt:

This letter corrects our substantially equivalent letter of May 23, 1996.

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 (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 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.

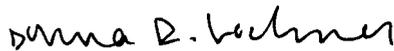
Page 2 - Mr. R. Larry Pratt

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 continue 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 (240) 276-0120. 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 (240) 276-3150 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): K960532

Device Name: Gore PRECLUDE IMA Sleeve

Indications For Use: For use as a wrap for pedicled arterial conduits.

Intended Use: The device identifies and protects pedicled arterial conduits during reoperative cardiac surgery.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Danna R. Vachon
(Division **1** Sign-Off)
Division of Cardiovascular Devices

510(k) Number K960532

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K960532

V. 510(k) Summary

MAY 23 1986

A. Submitted By: W.L. Gore & Associates, Inc.
Flagstaff, AZ 86002

Contact: R. Larry Pratt
520-779-2771

B. Device Name: PRECLUDE™ IMA Sleeve

C. Applicant Device Description:

Biocompatible, expanded polytetrafluoroethylene (ePTFE) in sleeve configuration. The sleeve configuration allows a surgeon to use the device as is without the need to form and shape the device during surgical procedures. The sleeve has a nominal 17-24 mm internal diameter and a length of 10-20 cm.

D. Intended Use and Indications

A surgical membrane indicated for use as a cover and physical barrier of pedicled arterial conduits which are used as coronary artery bypass grafts. The device identifies and protects pedicled arterial conduits during reoperative cardiac surgery.

E. Predicate Device:

The surgical membrane, PRECLUDE™ Pericardial Membrane, is cited as a predicate device which has been found to be substantially equivalent through the premarket notification process.

F. Technological Characteristics:

The applicant device has the same intended use and the same indications as the predicate device.

The applicant device is manufactured using the same inert, biocompatible ePTFE material as the predicate device. Mechanical strength test results show the applicant device to have material characteristics which are substantially equivalent to the predicate device.

	<u>Applicant</u>	<u>Predicate</u>
Mean Suture Pull-Out Force	0.67 kg	0.93 kg
Mean Peak Load	9.56 kg	4.49 kg

Data from animal studies show the applicant device to exhibit no histopathological complications and to have tissue attachment characteristics consistent with the predicate device.

G. Safety and Effectiveness Conclusions:

The applicant PRECLUDE™ IMA Sleeve is equivalent in materials and manufacturing processes to the predicate PRECLUDE™ Pericardial Membrane. The applicant device is composed of the same inert, biocompatible expanded PTFE as the predicate device. As demonstrated in animal studies, tissue attachment characteristics and the histological reactions and effects of the applicant device are equivalent to those of the predicate device. Mechanical testing data reveal the applicant device has strength values which are substantially equivalent to the predicate device. The applicant device is subjected to essentially the same quality tests and quality criteria as is the predicate device. The packaging processes and materials used for the applicant device will not differ from those used for the predicate device. The applicant device will be sterilized using the same sterilization methods, utilize the same post-sterilization release criteria and have the same Sterility Assurance Level of $\leq 10^{-6}$ as the predicate device.

The sleeve feature of the applicant device does not affect the safety or effectiveness of the product. No new types of safety and effectiveness questions are raised by the applicant device when compared to the predicate device.