K955364 (P 1 of 2)

FEB - 1 1996

V. Summary of Safety and Effectiveness Information

A. Submitter: W.L. Gore and Associates
P.O. Box 500
Flagstaff, AZ 86002-0500

Contact: R. Larry Pratt
520-779-2771

B. Device Name: SEAMGUARD™ Staple Line Reinforcement Material

C. Applicant Device Description:

Biocompatible, expanded polytetrafluoroethylene (ePTFE) in sleeve form. The sleeve is configured for use with commercially available linear surgical staplers.

D. Intended Use and Indications:

The device is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using linear surgical staplers.

The device can be used to reinforce staple lines during lung resections, abdominal and thoracic wall repairs, gastric banding, muscle flap reinforcement, rectal and vaginal prolapse, pelvic floor reconstruction, urethral sling and diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, and umbilical hernias. The device may be used with anastomotic staplers and with non-anastomotic staplers.

E. Predicate Device:

PERI-STRIPS™ Staple Line Reinforcement-Sleeve Configuration is cited as a predicate device which has been found to 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 composed of inert, biocompatible ePTFE material which has an extensive history of safe and effective use in a variety of medical applications including soft tissue applications. Animal studies show no adverse histologic reactions in lung tissue.

K955364 (12 of 2)

Mechanical test results show the applicant device to have material strength which is sufficient to resist staple pull-through and to prevent significant damage to the integrity of the material. In the tests conducted, the mean staple failure (i.e., staple straightening) force was 0.91 kg and the mean material failure force of the applicant device was 2.01 kg. The data show that staples being used in the reinforcement procedure would fail prior to applicant device material failure.

G. Safety and Effectiveness Conclusions:

The applicant SEAMGUARD Staple Line Reinforcement Material is substantially equivalent to the predicate device with regard to intended use, indications and technological characteristics. No new types of safety and effectiveness questions are raised by the applicant device when compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

W.L. Gore & Associates, Incorporated
% Mr. R. Larry Pratt
Regulatory Affairs
3450 West Kiltie Avenue, P.O. Box 500
Flagstaff, Arizona 86002-0500

Re:K955364
Trade/Device Name: SEAMGUARD™ Staple Line Reinforcement Material
Regulation Number: 21 CFR § 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class 2
Product Code: OXD, FTL
Dated: November 17, 1995
Received: November 22, 1995

JUN - 6 2012

Dear Dr. Titus:

This letter corrects our substantially equivalent letter of February 1, 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 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.

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); medical

device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health