 K033671 p.1/3

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Proprietary Name:	GORE BIOABSORBABLE MESH
Common Name:	Bioabsorbable Mesh
Classification Name:	Mesh, surgical, polymeric
Device Classification:	Class II
Product Classification and Code:	878.3300, FTL
Classification Panel:	General and Plastic Surgery 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 Standardssmmary

Performance standards do not currently exist for these devices. None established under Section 514.

K033671 1 2/3

Device Description

The GORE BIOABSORBABLE MESH is used to reinforce soft tissue during the phases of wound healing by filling or bridging soft-tissue void spaces or defects. The GORE BIOABSORBABLE MESH elicits a physiological tissue response, which fills the defect with native tissue and gradually absorbs the device.

GORE® BIOABSORBABLE MESH is comprised of a microporous structure of synthetic bioabsorbable poly (67% glycolide: 33% trimethylene carbonate by weight) (PGA: TMC) copolymer fiber. This is the same material used in the predicate device (GORE DRAPEABLE ST Regenerative Membrane, K013346, cleared December 19, 2001 and SEAMGUARD, K030782 cleared April 21, 2003).

As packaged, the GORE BIOABSORBABLE MESH is a tailorable, bioabsorbable material intended to be a temporary bridge of defects until the absorptive nature of the device stimulates the body to fill the defect with native tissue. The device is available in sheets and preformed, three-dimensional shapes. The GORE BIOABSORBABLE MESH is provided STERILE for single use only.

Due to the absorptive nature of the GORE BIOABSORBABLE MESH, an overlay patch should be used in corrections requiring high strength (e.g., groin hernia repair)

Indication for Use

The GORE BIOABSORBABLE MESH is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BIOABSORBABLE MESH may be used include, but are not limited to:

Hernia repair (inguinal, femoral, umbilical, abdominal, diaphragmatic, incisional, epigastric, gastroesophageal, hiatal, intermuscular).

Colon, rectal, urethral, and vaginal prolapse

Muscle flap reinforcement

Perforated tissue repair

General tissue reconstruction's (pelvic floor, periosteum, thoracic wall, bladder, suture line reinforcement, tissue deficit, etc.)

 K033671 8/3/3

Substantially Equivalent Devices

In W. L. Gore & Associates, Inc.'s opinion, the GORE BIOABSORBABLE MESH is believed to be substantially equivalent to the following predicate devices currently in interstate commerce with respect to comparable features, materials of construction and intended use.

- SEAMGUARD Bioabsorbable Staple Line Reinforcement Material (W. L. Gore & Associates, Inc., Flagstaff, AZ) – K030782
- GORE DRAPEABLE ST Regenerative Membrane (W. L. Gore & Associates, Inc., Flagstaff, AZ) – K013346
- Vicryl (Ethicon Inc., Somerville, NJ) – K810428
- DePuy Restore® Orthobiologic Soft Tissue Implant (DePuy, Inc., Warsaw, IN) – K001738
- FortaGen (Organogenesis Inc., Canton, MA) – K021105

Summary of Studies

W. L. Gore & Associates, Inc. performed device integrity testing to support that the GORE BIOABSORBABLE MESH is equivalent to the predicate devices. All device integrity test results for the GORE BIOABSORBABLE MESH 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 W. L. Gore & Associates, Inc. GORE BIOABSORBABLE MESH through this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 1 2003

Mr. Brandon Hansen
Regulatory Affairs
Medical Products Division
W.L. Gore & Associates, Inc.
3450 West Kiltie lane
Flagstaff, Arizona 86002-0500

Re: K033671
Trade/Device Name: Gore Bioabsorbable Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: November 21, 2003
Received: November 24, 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) 594-4659. 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,

for Miriam C. Provost

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

 K033671

INDICATION FOR USE

510(k) Number (if known): _____

Device Name: GORE BIOABSORBABLE MESH

Intended Use / Indication For Use:

The GORE BIOABSORBABLE MESH is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BIOABSORBABLE MESH may be used include, but are not limited to:

Hernia repair (inguinal, femoral, umbilical, abdominal, diaphragmatic, incisional, epigastric, gastroesophageal, hiatal, intermuscular).

Colon, rectal, urethral, and vaginal prolapse

Muscle flap reinforcement

Perforated tissue repair

General tissue reconstruction's (pelvic floor, periosteum, thoracic wall, bladder, suture line reinforcement, tissue deficit, etc.).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033671

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2009

W.L. Gore & Associates, Inc.
% Ms. Barbara L. Smith
Regulatory Associate
301 Airport Road, P.O. Box 1408
Elkton, Maryland 21922-1408

Re: K033671/A02
Device Name: GORE Bioabsorbable Hernia Plug
Dated: April 7, 2009
Received: April 13, 2009

Dear Ms. Smith:

We have reviewed the information dated April 7, 2009, regarding the 510(k) notification K033671 previously submitted for the device referenced above. Based solely on the change or modification that you have described, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). Additionally, we did not review any data submitted with this add to file. It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). Please refer to our guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device" at www.fda.gov/cdrh/ode/510kmod.html. The information you have supplied will be added to the file.

Sincerely yours,

for Peter Pfendler Dec 4/21/09

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Due 4/27/09

Date: 4/14/09

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K033671/A2

To: Division Director: SU/DSRD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checl below.

✓ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: David Krause

Date: April 20, 2009

cyer PAA 5/12/09 DMC 4/22

K033671/12

W. L. GORE & ASSOCIATES, INC.
301 Airport Road P.O. BOX 1408 Elkton, MD 21922-1408
FAX: 410/506-7922

Creative Technologies Worldwide

April 7, 2009

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Subject: Add to File for K033671
Change in Product Brand name for GORE Bioabsorbable Hernia Plug

Dear Sir/Madam:

This is notification to update premarket notification file K033671 to reflect a change in the brand name for the plug configuration of Gore Bioabsorbable mesh. The current brand name, GORE Bioabsorbable Hernia Plug, is being changed for marketing purposes to, **GORE BIO-A Hernia Plug**. No changes have been made to the intended/indications for use, design, technology, and materials for the device as cleared under this pre-market notification. The labeling has been updated to reflect the new brand name. A copy of the labeling is attached for inclusion in the file.

Please feel free to contact me at (410) 506-8189 (b)(4) with any questions.

Sincerely,

Barbara L. Smith

Barbara L. Smith
Regulatory Associate

1122

12 x 45 mm

GORE BIO-A

HERNIA PLUG

REF Catalogue Number
12345678910

LOT Batch Code
12345678910

Use By
2012-11

en	GORE BIO-A Hernia Plug	hu	GORE BIO-A sérvdugó
bg	Запушалка за херния BIO-A на GORE	it	Tampone per ernia GORE BIO-A
cz	Kýlní zátka GORE BIO-A	lt	GORE BIO-A išvaržų plastikos kamštelis
dk	GORE BIO-A brokindlæg	no	GORE BIO-A brokktampong
nl	GORE BIO-A herniaplug	pl	Korek przepuklinowy GORE BIO-A
ee	Songakork GORE BIO-A	pt	Tampão para Hérnias GORE BIO-A
fi	GORE BIO-A -tyrätulppa	ro	Dop Herniar GORE BIO-A
fr	Tampon herniaire GORE BIO-A	sk	Zátka na prietrž GORE BIO-A
de	GORE BIO-A-Hernienplombe	es	Tapón de hernia GORE BIO-A
gr	GORE BIO-A Πώμα Κήλης	se	GORE BIO-A bråckplugg

Attention, See Instructions for Use

Do Not Reuse

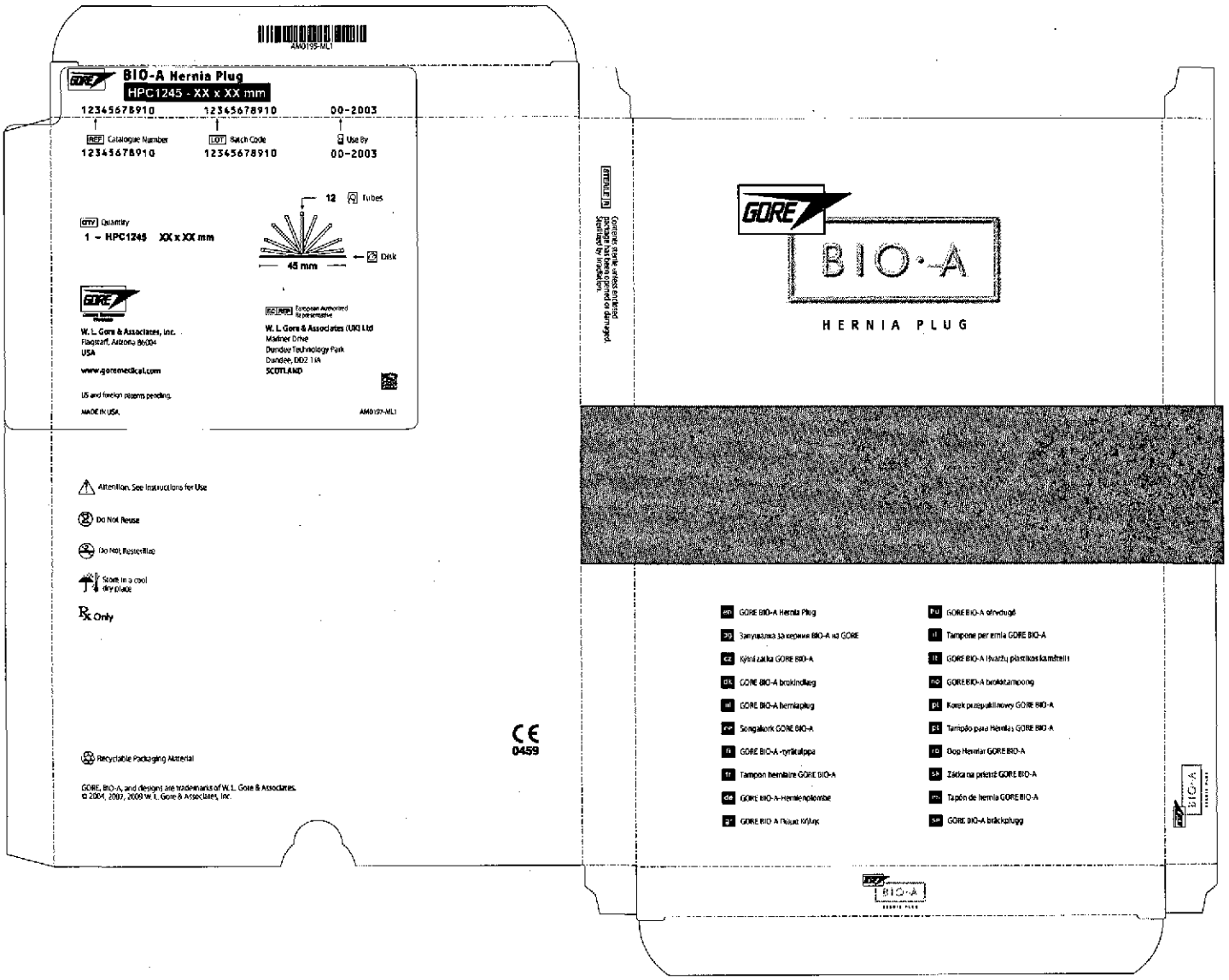
Do Not Resterilize

STERILE Contents sterile unless package has been opened or damaged.

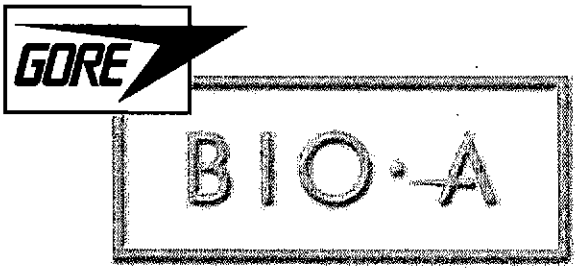
AM0198-ML1

Rx Only

CE 0459



INSTRUCTIONS FOR USE FOR:



HERNIA PLUG

en English	hu Magyar
bg Български	it Italiano
cz Čeština	lt Lietuvių
dk Dansk	no Norsk
nl Nederlands	pl Polska
ee Eesti	pt Português
fi Suomi	ro Română
fr Français	sk Slovenčina
de Deutsch	es Español
gr Ελληνικά	se Svenska

en

INSTRUCTIONS FOR USE
GORE BIO-A Hernia Plug

INTENDED USE
The GORE BIO-A Hernia Plug is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BIO-A Hernia Plug may be used include, but are not limited to, hernia repair (groin, abdominal and umbilical regions).

CONTRAINDICATIONS
NOT FOR RECONSTRUCTION OF CARDIOVASCULAR DEFECTS.

DESCRIPTION
As packaged, the GORE BIO-A Hernia Plug is a tailorable, bioabsorbable material intended to be a temporary bridge of defects until the bioabsorbable nature of the device allows the body to fill the defect with native tissue. The device is comprised of a disk attached to multiple tubes.

The implanted GORE BIO-A Hernia Plug is a porous fibrous structure composed solely of synthetic bioabsorbable poly(glycolide: trimethylene carbonate) copolymer. Degraded via a combination of hydrolytic and enzymatic pathways, the copolymer has been found to be both biocompatible and nonantigenic. In vitro studies indicate that the GORE BIO-A Hernia Plug can be expected to retain measurable mechanical strength through 4-5 weeks.

In vivo studies indicate the bioabsorption process should be complete by the end of 6 months.[1]

In repairs requiring high strength, an overlay patch is strongly recommended.

The GORE BIO-A Hernia Plug is provided STERILE for single use only. The GORE BIO-A Hernia Plug has been sterilized by gamma radiation. Provided the package is stored at room temperature and is not compromised in any way, it will serve as an effective barrier until the "use by" (expiration) date printed on the box.

PRECAUTIONS
- Due to the bioabsorbable nature of the GORE BIO-A Hernia Plug, an overlay patch is strongly recommended for those repairs which have a high strength requirement.
- Do not resterilize the GORE BIO-A Hernia Plug.
- Use of multiple GORE BIO-A Hernia Plugs in a single repair has not been reported.
- The MINIPAX® desiccant pouch included in the device package is not for implantation.
- If the MINIPAX® desiccant pouch has been compromised, discard product.

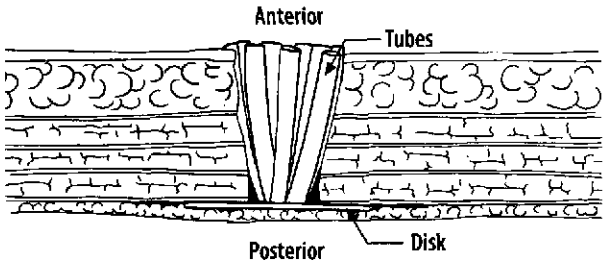
ADVERSE REACTIONS
Possible adverse reactions may include, but are not limited to, infection, inflammation, adhesions and seroma formation.

en

INSTRUCTIONS

For all uses, the GORE BIO-A Hernia Plug can be tailored with sharp surgical scissors to fit the specific defect size. In repairs requiring high strength (e.g., groin hernia repair), an overlay patch is strongly recommended.

In instances where the defect passes through a major tissue plane, the preformed GORE BIO-A Hernia Plug is inserted, disk first, into the defect.



The disk will temporarily collapse during passage through the tissue. Once the disk has entered a space (e.g., the preperitoneal space in inguinal hernia repair), the disk will expand to its original diameter. (NOTE: In instances where a space does not exist, finger dissection may be required, or the device can be trimmed to fit the void space). Once the disk has fully expanded, withdraw the device slightly to obtain purchase of the disk on the posterior wall of the defect. The tubes of the device can then be suture-tacked to the sides of the defect for stabilization.

REFERENCE

[1] Katz AR, Mukherjee DP, Kaganov AL, Gordon S. A new synthetic monofilament absorbable suture made from polytrimethylene carbonate. *Surgery, Gynecology & Obstetrics* 1985;161(3):213-222.

DEFINITIONS

Use By

Attention, See Instructions for Use

Do Not Re-Use

REF Catalogue Number

LOT Batch Code

EC REP European Authorized Representative

STERILE

Contents sterile unless package has been opened or damaged.

STERILE R

Contents sterile unless enclosed package has been opened or damaged. Sterilized by irradiation.

Disk

Do Not Resterilize

QTY Quantity

℞ Only CAUTION: USA Federal Law restricts the sale, distribution,or use of this device to, by, or on the order of a physician.

Store in a cool dry place

Tubes

W. L. Gore & Associates, Inc.
Flagstaff, Arizona 86004 • USA
Order Information: Tel.: 928.526.3030 • Tel.: 800.528.8763
Technical Information: Tel.: 928.779.2771 • Tel.: 800.437.8181

For international contact and additional product information,
visit **www.goremedical.com**

CE
0459

APRIL 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 5/9/08

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K033671/A1

To: Division Director: Sue Gardner

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below:

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

__✓__ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number). Device Name change

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: David Krause

Date: May 15, 2008

K033671/A1

W. L. GORE & ASSOCIATES, INC.
Creative Technologies Worldwide
301 Airport Road P.O. BOX 1408 Elkton, MD 21922-1408
FAX: 410/506-7922

May 8, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Subject: Add to File for K033671
Notification of Product Brand names for GORE Bioabsorbable Mesh devices

Dear Sir/Madam:

This is notification to the Agency of brand names used by W. L. Gore & Associates, Inc. for the devices cleared under the Gore Bioabsorbable Mesh device 510(k) number K033671, procode FTL. The three-dimensional configurations are marketed under the brand name of **GORE Bioabsorbable Hernia Plug**. The two-dimensional configurations are marketed under the brand name of **GORE BIO-A Tissue Reinforcement**. No changes have been made to the intended/indications for use, design, technology, materials or principals of operation for the device as cleared under this Pre-market Notification [510(k)].

A copy of the labeling for these devices is attached for reference.

Please feel free to contact me at (410) 506-8189 (b)(4) [redacted] with any questions.

Sincerely,

Barbara L. Smith
Regulatory Associate

K12

INSTRUCTIONS FOR USE FOR:

BIO-ABSORBABLE

HERNIA PLUG

GORE

en
English

dk
Dansk

nl
Nederlands

fi
Suomi

fr
Français

de
Deutsch

gr
Ελληνικά

it
Italiano

no
Norsk

pt
Português

es
Español

se
Svensk

en

INSTRUCTIONS FOR USE

GORE BIOABSORBABLE HERNIA PLUG

INTENDED USE

The GORE Bioabsorbable Hernia Plug is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE Bioabsorbable Hernia Plug may be used include, but are not limited to, hernia repair (groin, abdominal and umbilical regions).

CONTRAINDICATIONS

NOT FOR RECONSTRUCTION OF CARDIOVASCULAR DEFECTS.

DESCRIPTION

As packaged, the GORE Bioabsorbable Hernia Plug is a tailorable, bioabsorbable material intended to be a temporary bridge of defects until the bioabsorbable nature of the device allows the body to fill the defect with native tissue. The device is comprised of a disk attached to multiple tubes.

The implanted GORE Bioabsorbable Hernia Plug is a porous fibrous structure composed solely of synthetic bioabsorbable poly(glycolide: trimethylene carbonate) copolymer. Degraded via a combination of hydrolytic and enzymatic pathways, the copolymer has been found to be both biocompatible and nonantigenic. In vitro studies indicate that the GORE Bioabsorbable Hernia Plug can be expected to retain measurable mechanical strength through 4-5 weeks.

In vivo studies indicate the bioabsorption process should be complete by the end of 6 months.[1]

In repairs requiring high strength, an overlay patch is strongly recommended.

The GORE Bioabsorbable Hernia Plug is provided STERILE for single use only. The GORE Bioabsorbable Hernia Plug has been sterilized by gamma radiation. Provided the package is stored at room temperature and is not compromised in any way, it will serve as an effective barrier until the "use by" (expiration) date printed on the box.

PRECAUTIONS

- Due to the bioabsorbable nature of the GORE Bioabsorbable Hernia Plug, an overlay patch is strongly recommended for those repairs which have a high strength requirement.
- Do not resterilize the GORE Bioabsorbable Hernia Plug.
- Use of multiple GORE Bioabsorbable Hernia Plugs in a single repair has not been reported.
- The MiniPax® desiccant pouch included in the device package is not for implantation.
- If the MiniPax® desiccant pouch has been compromised, discard product.

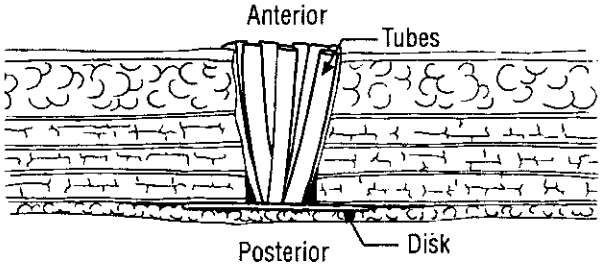
ADVERSE REACTIONS

Possible adverse reactions may include, but are not limited to, infection, inflammation, adhesions and seroma formation.

INSTRUCTIONS

For all uses, the GORE Bioabsorbable Hernia Plug can be tailored with sharp surgical scissors to fit the specific defect size. In repairs requiring high strength (e.g., groin hernia repair), an overlay patch is strongly recommended.

In instances where the defect passes through a major tissue plane, the preformed GORE Bioabsorbable Hernia Plug is inserted, disk first, into the defect.



The disk will temporarily collapse during passage through the tissue. Once the disk has entered a space (e.g., the preperitoneal space in inguinal hernia repair), the disk will expand to its original diameter. (NOTE: In instances where a space does not exist, finger dissection may be required, or the device can be trimmed to fit the void space). Once the disk has fully expanded, withdraw the device slightly to obtain purchase of the disk on the posterior wall of the defect. The tubes of the device can then be suture-tacked to the sides of the defect for stabilization.

REFERENCE

1 Katz AR, Mukherjee DP, Kaganov AL, Gordon S. A new synthetic monofilament absorbable suture made from polytrimethylene carbonate. *Surgery, Gynecology & Obstetrics* 1985;161(3):213-222.

DEFINITIONS

Use By

Attention, See Instructions for Use

Do Not Reuse

REF Catalogue Number

LOT Batch Code

EU REP European Authorized Representative

STERILE
Contents sterile unless enclosed package has been opened or damaged.

STERILE R
Contents sterile unless enclosed package has been opened or damaged. Sterilized by irradiation.

Disk

QTY Quantity

Store in a cool dry place

Tubes

AH1558-ML1

GORE
Creative Technologies Worldwide

W. L. Gore & Associates, Inc.
Flagstaff, Arizona 86003-3200
USA

Order Information:
Tel.: 928 / 526-3030
Tel.: 800 / 528-8763

Technical Information:
Tel.: 928 / 779-2771
Tel.: 800 / 437-8181

goremedical.com

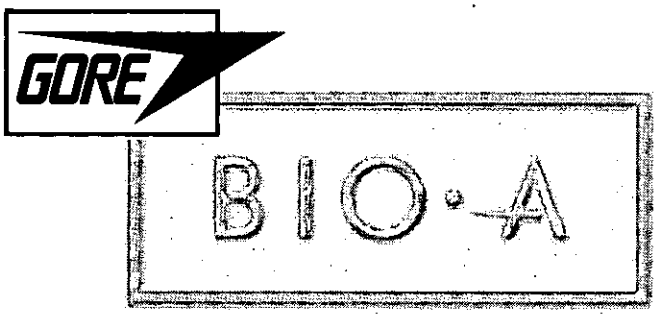
W. L. Gore & Associés, S.A.R.L.
Bercy International
20, place des vins de France
75012 PARIS
FRANCE

Tél.: +33 / 1-56-95-65-65
Fax: +33 / 1-56-95-64-00
+33 / 1-56-95-65-66
Numéro vert: 0800 / 14 17 02

CE
0459

FEBRUARY 2005

INSTRUCTIONS FOR USE FOR:



TISSUE
REINFORCEMENT

en

INSTRUCTIONS FOR USE

GORE BioA Tissue Reinforcement

INTENDED USE

The GORE BioA Tissue Reinforcement is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BioA Tissue Reinforcement may be used include, but are not limited to, hernia repair (in non-load bearing applications), muscle flap reinforcement, and general tissue reconstructions.

CONTRAINDICATIONS

NOT FOR RECONSTRUCTION OF CARDIOVASCULAR DEFECTS.

DESCRIPTION

As packaged, the GORE BioA Tissue Reinforcement is a tailorable, bioabsorbable material intended to be a temporary bridge of defects until the bioabsorbable nature of the device allows the body to fill the defect with native tissue.

The implanted GORE BioA Tissue Reinforcement is a porous fibrous structure composed solely of synthetic bioabsorbable poly(glycolide: trimethylene carbonate) copolymer. Degraded via a combination of hydrolytic and enzymatic pathways, the copolymer has been found to be both biocompatible and nonantigenic. *In vivo* studies indicate the bioabsorption process should be complete by the end of 6 months.[1]

In repairs requiring high strength, a permanent overlay patch is strongly recommended.

The GORE BioA Tissue Reinforcement is provided STERILE for single use only. The GORE BioA Tissue Reinforcement has been sterilized by gamma radiation. Provided the package is stored at room temperature and is not compromised in any way, it will serve as an effective barrier until the "use by" (expiration) date printed on the box.

PRECAUTIONS

- The GORE BioA Tissue Reinforcement is not designed to be a load-bearing prosthesis.
- Due to the bioabsorbable nature of the GORE BioA Tissue Reinforcement, a permanent overlay patch is strongly recommended for those repairs which have a high strength requirement.
- Do not resterilize the GORE BioA Tissue Reinforcement.
- The MiniPax® desiccant pouch included in the device package is not for implantation.
- If the MiniPax® desiccant pouch has been compromised, discard product.

ADVERSE REACTIONS

Possible adverse reactions may include, but are not limited to, infection, inflammation, adhesions and seroma formation.

INSTRUCTIONS

Using aseptic technique, trim the GORE BioA Tissue Reinforcement to the desired size using sharp surgical scissors. In repairs requiring high strength (e.g., groin hernia repair), a permanent overlay patch is strongly recommended. The GORE BioA Tissue Reinforcement may be suture-tacked to host tissue for stabilization.

The MiniPax® desiccant pouch included in the device package is not for implantation. If the MiniPax® desiccant pouch has been compromised, discard product.

REFERENCE

[1]Katz AR, Mukherjee DP, Kaganov AL,
Gordon S. A new synthetic monofilament absorbable suture made from polytrimethylene carbonate. *Surgery, Gynecology & Obstetrics* 1985;161(3):213-222.

DEFINITIONS

Use By

Attention, See Instructions for Use

Do Not Re-Use

REF Catalogue Number

LOT Batch Code

EC REP European Authorized Representative

STERILE

Contents sterile unless package has been opened or damaged.

STERILE R

Contents sterile unless enclosed package has been opened or damaged. Sterilized by irradiation.

Store in a cool dry place

AL0398-ML2

W. L. Gore & Associates, Inc.
Flagstaff, Arizona 86004 • USA
Order Information: Tel.: 928.526.3030 • Tel.: 800.528.8763
Technical Information: Tel.: 928.779.2771 • Tel.: 800.437.8181

For international contact and additional product information,
visit **www.goremedical.com**

CE
0459

Printed on recyclable paper

JANUARY 2008

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, Inc.
Medical Products Division
% Mr. Brandon Hansen, Regulatory Affairs
3450 West Kiltie Lane
Flagstaff, Arizona 86002-0500

JUL - 2 2012

Re: K033671
Trade/Device Name: GORE Bioabsorbable Mesh
Regulation Number: 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OWT, OWZ, OXC
Dated: November 21, 2003
Received: November 24, 2003

Dear Mr. Hansen:

This letter corrects our substantially equivalent letter of December 31, 2003.

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.

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

Enclosure

3-Mr. Brandon Hansen

(Please include 510(k) number here: (K033671)

Div/Branch	Last Name	Date	Div/Branch	Last Name	Date
DSORD/PRSB	Krumel	7/2/2012			
		9/2 11			

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
WO 66 (DSORD/PRSB)
D.O.
f/t:DXK:kdm:6/29/12

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table

 K033671 p.1/3

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Proprietary Name:	GORE BIOABSORBABLE MESH
Common Name:	Bioabsorbable Mesh
Classification Name:	Mesh, surgical, polymeric
Device Classification:	Class II
Product Classification and Code:	878.3300, FTL
Classification Panel:	General and Plastic Surgery 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 Standardssmmary

Performance standards do not currently exist for these devices. None established under Section 514.

K033671 1 2/3

Device Description

The GORE BIOABSORBABLE MESH is used to reinforce soft tissue during the phases of wound healing by filling or bridging soft-tissue void spaces or defects. The GORE BIOABSORBABLE MESH elicits a physiological tissue response, which fills the defect with native tissue and gradually absorbs the device.

GORE® BIOABSORBABLE MESH is comprised of a microporous structure of synthetic bioabsorbable poly (67% glycolide: 33% trimethylene carbonate by weight) (PGA: TMC) copolymer fiber. This is the same material used in the predicate device (GORE DRAPEABLE ST Regenerative Membrane, K013346, cleared December 19, 2001 and SEAMGUARD, K030782 cleared April 21, 2003).

As packaged, the GORE BIOABSORBABLE MESH is a tailorable, bioabsorbable material intended to be a temporary bridge of defects until the absorptive nature of the device stimulates the body to fill the defect with native tissue. The device is available in sheets and preformed, three-dimensional shapes. The GORE BIOABSORBABLE MESH is provided STERILE for single use only.

Due to the absorptive nature of the GORE BIOABSORBABLE MESH, an overlay patch should be used in corrections requiring high strength (e.g., groin hernia repair)

Indication for Use

The GORE BIOABSORBABLE MESH is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BIOABSORBABLE MESH may be used include, but are not limited to:

Hernia repair (inguinal, femoral, umbilical, abdominal, diaphragmatic, incisional, epigastric, gastroesophageal, hiatal, intermuscular).

Colon, rectal, urethral, and vaginal prolapse

Muscle flap reinforcement

Perforated tissue repair

General tissue reconstruction's (pelvic floor, periosteum, thoracic wall, bladder, suture line reinforcement, tissue deficit, etc.)

 K033671 8/3/3

Substantially Equivalent Devices

In W. L. Gore & Associates, Inc.'s opinion, the GORE BIOABSORBABLE MESH is believed to be substantially equivalent to the following predicate devices currently in interstate commerce with respect to comparable features, materials of construction and intended use.

- SEAMGUARD Bioabsorbable Staple Line Reinforcement Material (W. L. Gore & Associates, Inc., Flagstaff, AZ) – K030782
- GORE DRAPEABLE ST Regenerative Membrane (W. L. Gore & Associates, Inc., Flagstaff, AZ) – K013346
- Vicryl (Ethicon Inc., Somerville, NJ) – K810428
- DePuy Restore® Orthobiologic Soft Tissue Implant (DePuy, Inc., Warsaw, IN) – K001738
- FortaGen (Organogenesis Inc., Canton, MA) – K021105

Summary of Studies

W. L. Gore & Associates, Inc. performed device integrity testing to support that the GORE BIOABSORBABLE MESH is equivalent to the predicate devices. All device integrity test results for the GORE BIOABSORBABLE MESH 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 W. L. Gore & Associates, Inc. GORE BIOABSORBABLE MESH through this 510(k) Premarket Notification.

 K033671

INDICATION FOR USE

510(k) Number (if known): _____

Device Name: GORE BIOABSORBABLE MESH

Intended Use / Indication For Use:

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General tissue reconstruction's (pelvic floor, periosteum, thoracic wall, bladder, suture line reinforcement, tissue deficit, etc.).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033671

* * * COMMUNICATION RESULT REPORT (JUL. 21. 2012 11:13AM) * * *

FAX HEADER 1: FDA-CDRH-ODE-POS
FAX HEADER 2:

TRANSMITTED/STORED : JUL. 21. 2012 11:12AM

F	MODE	OPTION	ADDRESS	RESULT	PAGE
9201	MEMORY TX		4105068221	OK	3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

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, Inc.
Medical Products Division
% Mr. Brandon Hansen, Regulatory Affairs
3450 West Kiltie Lane
Flagstaff, Arizona 86002-0500

JUL – 2 2012

Re: K033671
Trade/Device Name: GORE Bioabsorbable Mesh
Regulation Number: 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OWT, OWZ, OXC
Dated: November 21, 2003
Received: November 24, 2003

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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

6/1/2012

PRSB

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 4/10

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K033671/A3

To: Division Director: SWI DSCRD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

X Other - Corrected SE

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: David Krane

Date: 6/29/2012

MEMORANDUM to the RECORD
K033671/A003

Date: June 29, 2012
From: David Krause, PhD, Expert Biologist & Branch Chief
Office/Division/Branch: ODE/DSORD/PRSB
Device: GORE Bioabsorbable Mesh
Applicant: W.L. Gore & Associates, Inc. of Elkton, Maryland
Contact: Michael J. Titus, Ph.D., Regulatory Affairs Associate
Phone: 410.506.8316
Facsimile: 410.506.8221

(b)(4)

(b)(4)

[redacted]

David Krause, PhD, Expert Biologist & Branch Chief
Division of Surgical, Orthopedic & Restorative Devices
Plastic & Reconstructive Surgery Branch

June 29, 2012
(Date)

Krause, David

From: (b)(4)
ent: Wednesday, June 27, 2012 8:08 AM
.o: Krause, David
Subject: Re: K033671/A03

Attachments: BioA Mesh revised summary final.doc; K033671 Revised Indication Statement.DOC


BioA Mesh revised summary fina...


K033671 Revised Indication Sta...

Hello again, David,

(b)(4)

 K033671 p.1/3

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Proprietary Name:	GORE BIOABSORBABLE MESH
Common Name:	Bioabsorbable Mesh
Classification Name:	Mesh, surgical, polymeric
Device Classification:	Class II
Product Classification and Code:	878.3300, FTL
Classification Panel:	General and Plastic Surgery 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 Standardssmmary

Performance standards do not currently exist for these devices. None established under Section 514.

K033671 1 2/3

Device Description

The GORE BIOABSORBABLE MESH is used to reinforce soft tissue during the phases of wound healing by filling or bridging soft-tissue void spaces or defects. The GORE BIOABSORBABLE MESH elicits a physiological tissue response, which fills the defect with native tissue and gradually absorbs the device.

GORE® BIOABSORBABLE MESH is comprised of a microporous structure of synthetic bioabsorbable poly (67% glycolide: 33% trimethylene carbonate by weight) (PGA: TMC) copolymer fiber. This is the same material used in the predicate device (GORE DRAPEABLE ST Regenerative Membrane, K013346, cleared December 19, 2001 and SEAMGUARD, K030782 cleared April 21, 2003).

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Due to the absorptive nature of the GORE BIOABSORBABLE MESH, an overlay patch should be used in corrections requiring high strength (e.g., groin hernia repair)

Indication for Use

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Muscle flap reinforcement

Perforated tissue repair

General tissue reconstruction's (pelvic floor, periosteum, thoracic wall, bladder, suture line reinforcement, tissue deficit, etc.)

 K033671 8/3/3

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- GORE DRAPEABLE ST Regenerative Membrane (W. L. Gore & Associates, Inc., Flagstaff, AZ) – K013346
- Vicryl (Ethicon Inc., Somerville, NJ) – K810428
- DePuy Restore® Orthobiologic Soft Tissue Implant (DePuy, Inc., Warsaw, IN) – K001738
- FortaGen (Organogenesis Inc., Canton, MA) – K021105

Summary of Studies

W. L. Gore & Associates, Inc. performed device integrity testing to support that the GORE BIOABSORBABLE MESH is equivalent to the predicate devices. All device integrity test results for the GORE BIOABSORBABLE MESH 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 W. L. Gore & Associates, Inc. GORE BIOABSORBABLE MESH through this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 1 2003

Mr. Brandon Hansen
Regulatory Affairs
Medical Products Division
W.L. Gore & Associates, Inc.
3450 West Kiltie lane
Flagstaff, Arizona 86002-0500

Re: K033671
Trade/Device Name: Gore Bioabsorbable Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: November 21, 2003
Received: November 24, 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.

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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) 594-4659. 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,

for Miriam C. Provost

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

Indications for Use

510(k) Number (if known): K033671

Device Name: GORE® Bioabsorbable Mesh

Indications For Use:

The GORE BIOABSORBABLE MESH is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BIOABSORBABLE MESH may be used include, but are not limited to:

Hernia repair (inguinal, femoral, umbilical, abdominal, diaphragmatic, incisional, epigastric, gastroesophageal, hiatal, intermuscular).

Muscle flap reinforcement

Perforated tissue repair

General tissue reconstruction's (periosteum, thoracic wall, reinforcement of the bladder wall, suture line reinforcement, tissue deficit, etc.)

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K033671 | A3

April 3, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Modification of indications for use for file 510(k) Premarket Notification #K033671

(b)(4)

[redacted]

W. L. GORE & ASSOCIATES, INC.
MEDICAL PRODUCTS DIVISION
301 AIRPORT ROAD • P.O. BOX 1408
ELKTON, MD 21922-1408 • U.S.
PHONE 410.392.3500 • FAX 410.506.7922
gore.com

I have included a modified 510(k) Indication statement form as an attachment with the above modified statement. If there are any questions concerning this request, please contact me directly at your convenience.

Sincerely yours,

Michael J. Titus

Michael J. Titus, Ph.D.
Regulatory Affairs Associate
W.L. Gore & Associates, Inc.
301 Airport Road, P.O. Box 1408
Elkton, Maryland 21922
410-506-8316
(b)(4)

cc: Mary Beth Ritchey, Ph.D.
Associate Director for Postmarket Surveillance Studies
Center for Devices and Radiological Health
MaryElizabeth.Ritchey@fda.hhs.gov

Attachment: Indications for Use – K033671

Indications for Use

510(k) Number (if known): K033671

Device Name: GORE® Bioabsorbable Mesh

Indications For Use:

The GORE BIOABSORBABLE MESH is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BIOABSORBABLE MESH may be used include, but are not limited to:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 1 2003

Mr. Brandon Hansen
Regulatory Affairs
Medical Products Division
W.L. Gore & Associates, Inc.
3450 West Kiltie lane
Flagstaff, Arizona 86002-0500

Re: K033671
Trade/Device Name: Gore Bioabsorbable Mesh
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Sincerely yours,

Miriam C. Provost
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

 K033671

INDICATION FOR USE

510(k) Number (if known): _____

Device Name: GORE BIOABSORBABLE MESH

Intended Use / Indication For Use:

The GORE BIOABSORBABLE MESH is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BIOABSORBABLE MESH may be used include, but are not limited to:

Hernia repair (inguinal, femoral, umbilical, abdominal, diaphragmatic, incisional, epigastric, gastroesophageal, hiatal, intermuscular).

Colon, rectal, urethral, and vaginal prolapse

Muscle flap reinforcement

Perforated tissue repair

General tissue reconstruction's (pelvic floor, periosteum, thoracic wall, bladder, suture line reinforcement, tissue deficit, etc.).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(510(k) Number) K033671

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

November 25, 2003

W. L. GORE & ASSOCIATES, INC.
MEDICAL PRODUCTS DIVISION
3450 WEST KILTIE LN.
FLAGSTAFF, AZ 86002
ATTN: BRANDON HANSEN

510(k) Number: K033671
Received: 24-NOV-2003
Product: GORE BIOABSORBABLE MESH

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/oc/mdufma).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K 033671

W. L. GORE & ASSOCIATES, INC.

Creative Technologies Worldwide

3450 WEST KILTIE LANE • FLAGSTAFF, ARIZONA 86001
PHONE: 928/779-2771 • FAX: 928/779-3480
MEDICAL PRODUCTS DIVISION

November 21, 2003

FDA/CDRH/OCE/PMO
2003 NOV 24 A 10:00

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: 510(k) Premarket Notification: GORE BIOABSORBABLE MESH

To Whom It May Concern:

W. L. Gore & Associates, Inc., hereby submits this 510(k) Premarket Notification on behalf of the GORE BIOABSORBABLE MESH.

Through data and information presented herein, numerous similarities with the predicate devices identified in this submission, support a determination of substantial equivalence, and therefore market clearance of the W. L. Gore & Associates, Inc. GORE BIOABSORBABLE MESH.

In accordance with 21 CFR Part 807.90(c), this 510(k) Premarket Notification is being submitted in duplicate. This submission contains confidential and trade secret information and W. L. Gore & Associates, Inc. respectfully requests that FDA not disclose the existence of this Premarket Notification of its contents under the provisions of 21 CFR Part 807.95.

Please feel free to contact the undersigned with any questions related to the enclosed information.

Regards,

W. L. GORE & ASSOCIATES, INC.

Brandon Hansen
Regulatory Affairs
Medical Products Division

Telephone: (928) 864-3784
Facsimile: (928) 864-4144
(b)(4)

SU II

Confidential

Sk 2 13

Form Approved:OMB No. 0910-0511 Expiration Date: (b)(4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER
Write the Payment Identification Numb

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)

W. L. GORE & ASSOCIATES, INC.
3450 WEST KILTIE LANE
FLAGSTAFF, AZ 86001

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
510083365

2. CONTACT NAME
BRANDON HANSEN

(b)(4)

2.2 TELEPHONE NUMBER (Include Area Code)
928-864-3784

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)
928-864-4144

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
- ☑ Premarket notification (510(k)); except for third party reviews
- ☐ Biologics License Application (BLA)
- ☐ Premarket Approval Application (PMA)
- ☐ Modular PMA
- ☐ Product Development Protocol (PDP)
- ☐ Premarket Report (PMR)

3.1 Select one of the types below:
- ☑ Original Application

Supplement Types:
- ☐ Efficacy (BLA)
- ☐ Panel Track (PMA, PMR, PDP)
- ☐ Real-Time (PMA, PMR, PDP)
- ☐ 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

- ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- ☑ NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE **EXCEPTIONS**? IF SO, CHECK THE APPLICABLE EXCEPTION.

- ☐ This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- ☐ The sole purpose of the application is to support conditions of use for a pediatric population
- ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

☐ YES ☑ NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)

(b)(4)

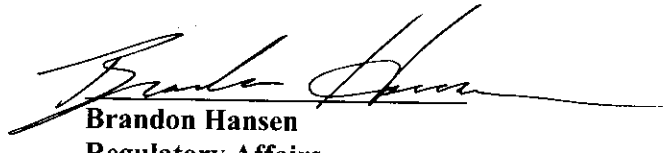
14

PREMARKET NOTIFICATION

GORE BIOABSORBABLE MESH

Submitted by: W. L. Gore & Associates, Inc.

Medical Products Division
3450 West Kiltie Lane
Flagstaff, AZ 86002-0500



Brandon Hansen
Regulatory Affairs

November 21, 2003

Table of Contents

TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my respective capacity as Regulatory Affairs or Product Specialist of WL Gore & Associates, Inc., that all data and information submitted in this 510(k) Premarket Notification are truthful and accurate and that no material fact has been omitted.

Brandon Hansen
Regulatory Affairs
Medical Products Division
W. L. Gore & Associates, Inc.

William Montgomery
Product Specialist
Medical Products Division
W. L. Gore & Associates, Inc.

November 21, 2003

CONFIDENTIALITY STATEMENT

This submission contains confidential commercial and trade secret information. This is to advise you that certain information contained in this 510(k) submission, which has been printed on paper marked "Confidential" is being submitted under express claim of confidentiality. It is W. L. Gore & Associate's position that this information is exempt from mandatory disclosure under Exemption 4 of the Freedom of Information Act, USC Section 1905. This information is not available to our competitors. Disclosure would have an adverse impact on W. L. Gore & Associate's competitive position.

If any person requests an inspection or requests a copy of the documents or any portion of them under the Freedom of Information Act, please give W. L. Gore & Associates sufficient advance notice prior to any such disclosure to allow us to pursue appropriate remedies to preserve the confidentiality of this information.

Brandon Hansen
Regulatory Affairs
Medical Products Division
W. L. Gore & Associates, Inc.

November 21, 2003

INDICATION FOR USE

510(k) Number (if known): _____

Device Name: GORE BIOABSORBABLE MESH

Intended Use / Indication For Use: The GORE BIOABSORBABLE MESH is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BIOABSORBABLE MESH may be used include, but are not limited to:

Hernia repair (inguinal, femoral, umbilical, abdominal, diaphragmatic, incisional, epigastric, gastroesophageal, hiatal, intermuscular).

Colon, rectal, urethral, and vaginal prolapse

Muscle flap reinforcement

Perforated tissue repair

General tissue reconstruction's (pelvic floor, periosteum, thoracic wall, bladder, suture line reinforcement, tissue deficit, etc.).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use

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

SUMMARY OF 21 CFR 807.87

Proprietary Name:	GORE BIOABSORBABLE MESH
Common Name:	Bioabsorbable Mesh
Classification Name:	Mesh, surgical, polymeric
Device Classification:	Class II
Product Classification and Code:	878.3300, FTL
Classification Panel:	General and Plastic Surgery 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 (b)(4) [redacted]

Performance Standards

Performance standards do not currently exist for these devices. None established under Section 514.

(b)(4) [redacted]

Device Sterilizer

(b)(4)

[redacted]

Purpose of Submission

The purpose of this 510(k) Premarket Notification submission is to market GORE BIOABSORBABLE MESH which W. L. Gore & Associates, Inc. believes to be substantially equivalent to the following predicate devices:

- SEAMGUARD Bioabsorbable Staple Line Reinforcement Material (W. L. Gore & Associates, Inc., Flagstaff, AZ) – K030782
- GORE DRAPEABLE ST Regenerative Membrane (W. L. Gore & Associates, Inc., Flagstaff, AZ) – K013346
- Vicryl (Ethicon Inc., Somerville, NJ) – K810428
- DePuy Restore® Orthobiologic Soft Tissue Implant (DePuy, Inc., Warsaw, IN) – K001738
- FortaGen (Organogenesis Inc., Canton, MA) – K021105

510(k) Summary of Substantial Equivalence

In response to the requirements addressed by the Safe Medical Device Act of 1990, a 510(k) summary of the information upon which the substantial equivalence determination is based may be found in the 510(k) Summary of Substantial Equivalence section.

Draft Labeling

As applicable, applicant device draft labeling for GORE BIOABSORBABLE MESH complies with 21 CFR 801. See Attachment A for applicant device draft labeling.

DEVICE DESCRIPTION

The GORE BIOABSORBABLE MESH is used to reinforce soft tissue during the phases of wound healing by filling or bridging soft-tissue void spaces or defects. The GORE BIOABSORBABLE MESH elicits a physiological tissue response, which fills the defect with native tissue and gradually absorbs the device.

(b)(4)

[redacted]

As packaged, the GORE BIOABSORBABLE MESH is a tailorable, bioabsorbable material intended to be a temporary bridge of defects until the absorptive nature of the device allows the body to fill the defect with native tissue. The device is available in sheets and preformed, three-dimensional shapes. The GORE BIOABSORBABLE MESH is provided STERILE for single use only.

Due to the absorptive nature of the GORE BIOABSORBABLE MESH, a supplemental overlay patch should be used in corrections requiring high strength (e.g., groin hernia repair).

(b)(4)

Sheet Configuration

(b)(4)

Plug Configuration

(b)(4)

[redacted]

SUBSTANTIAL EQUIVALENCE COMPARISON

W. L. Gore & Associates, Inc. believes the GORE BIOABSORBABLE MESH to be substantially equivalent to the predicate devices currently in interstate commerce listed below and in Table 2.

Indication / Intended Uses:

The following products have similar indications for use as a bioabsorbable mesh.

Vicryl (Ethicon Inc., Somerville, NJ) – K810428

FDA cleared Vicryl in 1981 under 510(k) K810428. VICRYL (polyglactin 910) woven mesh is prepared from a synthetic absorbable copolymer of glycolide and lactide, derived respectively from glycolic and lactic acids. This tightly woven mesh is prepared from uncoated, undyed fiber identical in composition to that used in VICRYL (polyglactin 910) synthetic absorbable suture, which has been found to be inert, nonantigenic, nonpyrogenic and to elicit only a mild tissue reaction during absorption. VICRYL woven mesh is intended for use as a buttress to provide temporary support during the healing process.

VICRYL woven mesh may be used wherever temporary wound or organ support is required. The woven mesh structure is less porous than VICRYL knitted mesh. It is indicated in instances in which containment of wound transudate is desirable. VICRYL woven mesh may be cut to the shape or size desired for each specific application.

VICRYL knitted mesh may be used wherever temporary wound or organ support is required, particularly in instances in which complaint and stretchable support material is desired and containment of wound transudate is not required. VICRYL knitted mesh may be cut to the shape or size desired for each specific application.

VICRYL woven mesh is available in single packets as a sterile, undyed, fabric mesh in single sheet sizes of approximately 6 x 6 inches and 12 x 12 inches (15 x 15 centimeters and 30 x 30 centimeters).

DePuy Restore® Orthobiologic Soft Tissue Implant (DePuy, Inc., Warsaw, IN) – K001738

FDA cleared DePuy Restore® Orthobiologic Soft Tissue Implant on December 27, 2000 under 510(k) K001738. The Restore Orthobiologic Soft Tissue Implant is a round device, manufactured from 10 plys of Small intestine Submucosa, (SIS). SIS is a biomaterial derived from porcine small intestine. SIS is composed predominately of water and collagen.

The Restore Orthobiologic Soft Tissue Implant is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists. The device is intended to act as a resorbable scaffold that initially has sufficient strength to assist with a soft tissue repair, but then resorbs and is replaced by the patient's own tissue. The device is also intended for reinforcement of the soft tissue which are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff surgery.

FortaGen (Organogenesis Inc., Canton, MA) – K021105

FDA cleared FortaGen on May 10, 2002 under 510(k) K021105. FortaGen consists of a multi-laminate sheet predominantly of Type I porcine collagen. The device is supplied in sheet form in sizes ranging from 5 x 5 cm to 12 x 36 cm in sterile double layer peelable packaging.

FortaGen is intended to be used for implantation to reinforce soft tissue including but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture-line reinforcement and reconstructive procedures. The device is intended for one-time use.

Technological Characteristics (Materials):

The following products are made of the same or similar synthetic material.

Vicryl (Ethicon Inc., Somerville, NJ) – K810428

FDA cleared Vicryl in 1981 under 510(k) K810428. VICRYL (polyglactin 910) woven mesh is prepared from a synthetic absorbable copolymer of glycolide and lactide, derived respectively from glycolic and lactic acids. This tightly woven mesh is prepared from uncoated, undyed fiber identical in composition to that used in VICRYL (polyglactin 910) synthetic absorbable suture, which has been found to be inert, nonantigenic, nonpyrogenic and to elicit only a mild tissue reaction during absorption. VICRYL woven mesh is intended for use as a buttress to provide temporary support during the healing process.

VICRYL woven mesh may be used wherever temporary wound or organ support is required. The woven mesh structure is less porous than VICRYL knitted mesh. It is indicated in instances in which containment of wound transudate is desirable. VICRYL woven mesh may be cut to the shape or size desired for each specific application.

VICRYL knitted mesh may be used wherever temporary wound or organ support is required, particularly in instances in which complaint and stretchable support material is desired and containment of wound transudate is not required. VICRYL knitted mesh may be cut to the shape or size desired for each specific application.

VICRYL woven mesh is available in single packets as a sterile, undyed, fabric mesh in single sheet sizes of approximately 6 x 6 inches and 12 x 12 inches (15 x 15 centimeters and 30 x 30 centimeters).

GORE DRAPEABLE ST Regenerative Membrane (Resolut ADAPT®) (W. L. Gore & Associates, Flagstaff, AZ) – K013346

The GORE DRAPEABLE ST Regenerative Membrane was cleared by FDA on December 19, 2001 under 510(k) K013346. The GORE DRAPEABLE ST Regenerative Membrane serves as a membrane for bone graft containment and provides a favorable environment for bone regeneration. It is comprised of a porous structure of synthetic bioabsorbable poly (glycolide: trimethylene carbonate) copolymer fiber (67% PGA: 33% TMC). This fiber web was designed to allow attachment to surrounding tissues.

The GORE DRAPEABLE ST Regenerative Membrane is supplied as a sterile, single use product in a foil pouch and is sterilized using gamma sterilization.

SEAMGUARD Bioabsorbable Staple Line Reinforcement Material (W. L. Gore & Associates, Flagstaff, AZ) – K030782

The SEAMGUARD Bioabsorbable Staple Line Reinforcement Material was cleared by FDA on April 21, 2003 under 510(k) K030782. The SEAMGUARD

Bioabsorbable Staple Line Reinforcement Material consists of a bioabsorbable membrane formed into a sleeve with use of a polyester braided suture pullcord. The bioabsorbable material is comprised of a microporous structure of synthetic bioabsorbable 67% PGA: 33% TMC copolymer. The SEAMGUARD Bioabsorbable Staple Line Reinforcement Material is to be used with surgical stapling devices.

Table 2: Substantial Equivalence

	Applicant Device (Subject of this Submission)	Predicate Devices Referenced in this Submission				
Manufacturer	(b)(4)	W. L. Gore & Associates, Inc.	W. L. Gore & Associates, Inc.	DePuy, Inc	Ethicon, Inc	Organogenesis, Inc.
Model Number		SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material	GORE DRAPEABLE ST Regenerative Membrane (Resolut ADAPT®)	DePuy Restore® Orthobiologic Soft Tissue Implant	Vicryl™	FortaGen
510(k) Number		K030782	K013346	K001738	K810428	K021105
Material		67% PGA: 33% TMC copolymer	67% PGA: 33% TMC copolymer	Small Intestine Submucosa (SIS) of porcine origin	90% PGA: 10% PLA copolymer	Type I porcine collagen
Sterilization Method		Gamma Radiation	Gamma Radiation	N/A	N/A	N/A
Packaging Materials		Peelable, laminated foil pouch, surgical grade paper, Tyvek carrier and cardboard box	Peelable (laminated foil pouch), surgical grade paper and cardboard box	N/A	N/A	N/A

RISK ANALYSIS / PERFORMANCE DATA

Risk Analysis

Risk analysis with the aid of Failure Modes and Effects Analysis (FMEA) of the GORE BIOABSORBABLE MESH has been initiated. This process is used to identify potential design inadequacies that may adversely affect safety and performance. Based on the results of the risk analysis, a Design Assurance test plan will be written and the applicable Design Verification tests will be performed to ensure that all potential risks due to the design of the device are evaluated.

Performance Data Testing

Mechanical Characterization

(b)(4)

[redacted]

(b)(4)

[redacted]

Biodegradation

(b)(4)

[redacted]

Animal Studies

(b)(4)

[redacted]

(b)(4)

[redacted]

STERILIZATION / PACKAGING INFORMATION

Sterilization Validation

(b)(4)

[redacted]

Sterility Assurance Level

(b)(4)

[redacted]

Sterile Packaging Materials

(b)(4)

[redacted]

Shelf Life and Expiration Dating

(b)(4)

[redacted]

Biocompatibility

(b)(4)

[redacted]

Table 3: Biocompatibility Information on Bioabsorbable Mesh Material

(b)(4)

[redacted]

Package Testing

(b)(4)

[redacted]

Software Validation / Verification

Software validation and verification activities do not apply to the GORE BIOABSORBABLE MESH, as there is no software contained within the product.

Software Hazard Analysis

Software hazard analysis does not apply to the GORE BIOABSORBABLE MESH, as there is no software contained within the product.

LABELING

As applicable, applicant device draft labeling for GORE BIOABSORBABLE MESH complies with 21 CFR 801. See Attachment A for applicant device draft labeling.

 K033671 p.1/3

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Proprietary Name:	GORE BIOABSORBABLE MESH
Common Name:	Bioabsorbable Mesh
Classification Name:	Mesh, surgical, polymeric
Device Classification:	Class II
Product Classification and Code:	878.3300, FTL
Classification Panel:	General and Plastic Surgery 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 Standardssmmary

Performance standards do not currently exist for these devices. None established under Section 514.

K033671 1 2/3

Device Description

The GORE BIOABSORBABLE MESH is used to reinforce soft tissue during the phases of wound healing by filling or bridging soft-tissue void spaces or defects. The GORE BIOABSORBABLE MESH elicits a physiological tissue response, which fills the defect with native tissue and gradually absorbs the device.

GORE® BIOABSORBABLE MESH is comprised of a microporous structure of synthetic bioabsorbable poly (67% glycolide: 33% trimethylene carbonate by weight) (PGA: TMC) copolymer fiber. This is the same material used in the predicate device (GORE DRAPEABLE ST Regenerative Membrane, K013346, cleared December 19, 2001 and SEAMGUARD, K030782 cleared April 21, 2003).

As packaged, the GORE BIOABSORBABLE MESH is a tailorable, bioabsorbable material intended to be a temporary bridge of defects until the absorptive nature of the device stimulates the body to fill the defect with native tissue. The device is available in sheets and preformed, three-dimensional shapes. The GORE BIOABSORBABLE MESH is provided STERILE for single use only.

Due to the absorptive nature of the GORE BIOABSORBABLE MESH, an overlay patch should be used in corrections requiring high strength (e.g., groin hernia repair)

Indication for Use

The GORE BIOABSORBABLE MESH is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BIOABSORBABLE MESH may be used include, but are not limited to:

Hernia repair (inguinal, femoral, umbilical, abdominal, diaphragmatic, incisional, epigastric, gastroesophageal, hiatal, intermuscular).

Colon, rectal, urethral, and vaginal prolapse

Muscle flap reinforcement

Perforated tissue repair

General tissue reconstruction's (pelvic floor, periosteum, thoracic wall, bladder, suture line reinforcement, tissue deficit, etc.)

 K033671 8/3/3

Substantially Equivalent Devices

In W. L. Gore & Associates, Inc.'s opinion, the GORE BIOABSORBABLE MESH is believed to be substantially equivalent to the following predicate devices currently in interstate commerce with respect to comparable features, materials of construction and intended use.

- SEAMGUARD Bioabsorbable Staple Line Reinforcement Material (W. L. Gore & Associates, Inc., Flagstaff, AZ) – K030782
- GORE DRAPEABLE ST Regenerative Membrane (W. L. Gore & Associates, Inc., Flagstaff, AZ) – K013346
- Vicryl (Ethicon Inc., Somerville, NJ) – K810428
- DePuy Restore® Orthobiologic Soft Tissue Implant (DePuy, Inc., Warsaw, IN) – K001738
- FortaGen (Organogenesis Inc., Canton, MA) – K021105

Summary of Studies

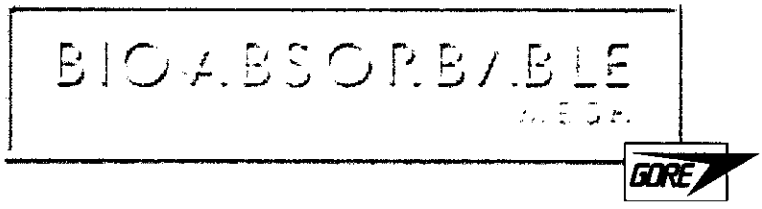
W. L. Gore & Associates, Inc. performed device integrity testing to support that the GORE BIOABSORBABLE MESH is equivalent to the predicate devices. All device integrity test results for the GORE BIOABSORBABLE MESH met specified requirements.

Conclusion (Statement of Equivalence)

Through data and information presented, numerous similarities support a determination of substantial equivalence, and therefore market clearance of the W. L. Gore & Associates, Inc. GORE BIOABSORBABLE MESH through this 510(k) Premarket Notification.

ATTACHMENT A –DEVICE LABELING

INSTRUCTIONS FOR USE FOR:



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English

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INSTRUCTIONS FOR USE

GORE BIOABSORBABLE MESH

INDICATIONS

The GORE Bioabsorbable Mesh is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE Bioabsorbable Mesh may be used include, but are not limited to:

1. Hernia repair (inguinal, femoral, umbilical, abdominal, diaphragmatic, incisional, epigastric, gastroesophageal, hiatal, intermuscular).
2. Colon, rectal, urethral, and vaginal prolapse
3. Muscle flap reinforcement
4. Perforated tissue repair
5. General tissue reconstructions (pelvic floor, periosteum, dura mater, thoracic wall, bladder, suture line reinforcement, tissue deficit, etc.)

CONTRAINDICATIONS

NOT FOR RECONSTRUCTION OF CARDIOVASCULAR DEFECTS.

DESCRIPTION

As packaged, the GORE Bioabsorbable Mesh is a tailorable, bioabsorbable material intended to be a temporary bridge of defects until the absorptive nature of the device stimulates the body to fill the defect with native tissue. The device is available in sheets and preformed, three-dimensional shapes.

The implanted GORE Bioabsorbable Mesh is a porous fibrous structure composed solely of synthetic bioabsorbable poly (glycolide: trimethylene carbonate) copolymer. Degraded via a combination of hydrolytic and enzymatic pathways, the copolymer has been found to be both biocompatible and nonantigenic, with a history of use as bioabsorbable sutures, membranes and other implantable devices. In-vitro studies indicate that the GORE Bioabsorbable Mesh can be expected to retain measurable mechanical strength through 4-5 weeks. In-vivo studies indicate the bioabsorption process should be complete by the end of 6 months.[1]

Due to the absorptive nature of the GORE Bioabsorbable Mesh, an overlay patch should be used in corrections requiring high strength (e.g., groin hernia repair).

This is a single use device and should not be resterilized.

PRECAUTIONS

- Due to the absorptive nature of the GORE Bioabsorbable Mesh device, an overlay patch (not provided) is strongly recommended for those repairs, which have a high strength requirement.
- Do not resterilize the GORE Bioabsorbable Mesh.
- Use of multiple devices in a single repair has not been reported.

ADVERSE REACTIONS

Possible adverse reactions may include, but are not limited to infection, inflammation, adhesions and hematoma.

INSTRUCTIONS

For all uses, the GORE Bioabsorbable Mesh can be tailored to fit the specific defect size. In repairs requiring high strength (e.g. groin hernia repair), an overlay patch is strongly recommended.

For Flat Sheets

Using aseptic technique, trim the GORE Bioabsorbable Mesh to the desired size using sharp surgical scissors. The GORE Bioabsorbable Mesh should be sutured or tacked to host tissue avoiding excessive tension.

For Preformed Shapes (Plug)

In instances where the defect passes through a major tissue plane, the preformed GORE Bioabsorbable Mesh is inserted, disk first, into the defect. The disk will temporarily collapse during passage through the tissue. Once the disk has entered a space (e.g. the preperitoneal space in inguinal hernia repair), the disk will expand to its original diameter. (NOTE: In instances where a space does not exist, finger dissection may be required, or the device can be trimmed to fit the void space). Once the disk has fully expanded, the device is withdrawn slightly to obtain purchase of the disk on the posterior wall of the defect. The tubes of the device can then be suture tacked to the sides of the defect for stabilization.

REFERENCE

[1] Katz AR, Mukherjee DP, Kaganov AL, Gordon S. A new synthetic monofilament absorbable suture made from polytrimethylene carbonate. Surgery, Gynecology & Obstetrics 1985;161(3):213-222.

en

DEFINITIONS

Use By

Attention, See Instructions for Use

Do Not Reuse

REF Catalogue Number

LOT Batch Code

EU REP European Authorized Representative

STERILE
Contents sterile unless package has been opened or damaged.

STERILE R
Contents sterile unless enclosed package has been opened or damaged. Sterilized by irradiation.

(1) Outer pouch is the only sterile barrier.

AG5066-EN1

W. L. Gore & Associates, Inc.
Flagstaff, Arizona 86003-3200
USA

Order Information:
Tel.: 928 / 526-3030
Tel.: 800 / 528-8763

Technical Information:
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Tel.: 800 / 437-8181

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Numéro vert: 0800 / 141702

CE
0459

NOVEMBER 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Herbert Lerner MD

Subject: 510(k) Number K033671

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 d

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

FTL 878.3300 Surgical Mesh CLASS II

Review: Stephen Ruder (Branch Chief) PRSB (Branch Code) 12/29/03 (Date)

Final Review: for Miriam C. Provost (Division Director) 12/30/03 (Date)

Revised:4/2/03

510 (k) Memorandum
K033671

To: The Record
From: Herbert Lerner, MD
Date: December 4, 2003
Subject: Gore Bioabsorbable Mesh
Sponsor: W. L. Gore & Associates, Inc.
Medical Products Division
3450 West Kiltie Ln.
Flagstaff, AZ 86002

Mr. Brandon Hansen
928-864-3784
bhansen@wlgore.com

Procode: FTL
Regulation: 21 CFR 878.3300
Surgical Mesh
Class: II

Predicates: K030782, K013346, K001738, K810428, K021105

Recommendation: Substantially Equivalent

The device contains no drugs or biologicals.

Indication for Use: The Gore Bioabsorbable Mesh is intended for use in the reinforcement of soft tissue. Examples of applications where the Mesh may be used include, but are not limited to:

- Hernis repair (inguinal, femoral, umbilical, abdominal, diaphragmatic, incisional, epigastric, gastroesophageal, hiatal, intermuscular)
- Colon, rectal, urethral, and vaginal prolapse
- Muscle flap reinforcement
- Perforated tissue repair
- General tissue reconstruction's (pelvic floor, periosteum, , thoracic wall, bladder, suture line reinforcement, tissue deficit, etc.)

The predicate devices have similar, if not related indications:

K030782- The Seamguard material is indicated for surgical procedures in which soft tissue transaction or resection with staple line reinforcement is needed.

K021105- the FortaGen is intended to be used for implantation to reinforce soft tissue including, but not limited to, defects of the abdominal and thoracic wall, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture-line reinforcement and reconstructive procedures.

K013346-Gore Drapable ST are intended to aid in the healing of periodontal and bone defects, or as a membrane for bone containment.

K001738- DePuy Restore Tissue Implant is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists. In addition, it is intended for use in the supraspinatus during rotator cuff repair surgery.

Summary: taken together, the indications of the subject device are included in those of the predicate, and taken as a whole, adequately support substantial equivalence. In the decision-making paradigm, the differences in indication do not alter the intended therapeutic/diagnostic effects, and do not have any effects on safety or effectiveness.

Technological Characteristics: (b)(4) [redacted]

K001738- porcine SIS material
K030782- same as subject device
K013346- same as subject device
K021105- porcine collagen (type I)
K810428- 90% PGA: 10% PLA copolymer

These differences do not affect safety or effectiveness, as they are all commonly used in a host of medical devices, and are equivalent.

(b)(4) [redacted]

Performance Data: Mechanical Characterization, Biodegredation, Animal Studies for tissue response, etc, are well documented in the previously cleared Gore products- Gore Drapable ST (K013346), Gore Resolut XT (K973594, K970884 and K962624), and Gore Seamguard (K030782). These studies are outlined in the submission and will not be repeated here.

Summary: There are no concerns for safety as the biocompatibility studies were performed on the predicate made of the exact material as this device and were adequate to clear the device.

Sterilization:

(b)(4) [redacted]

(b)(4)

[redacted]

Labeling:

Instructions for Use- Attachment A
Package labels- Attachment A
The device will be available by prescription.

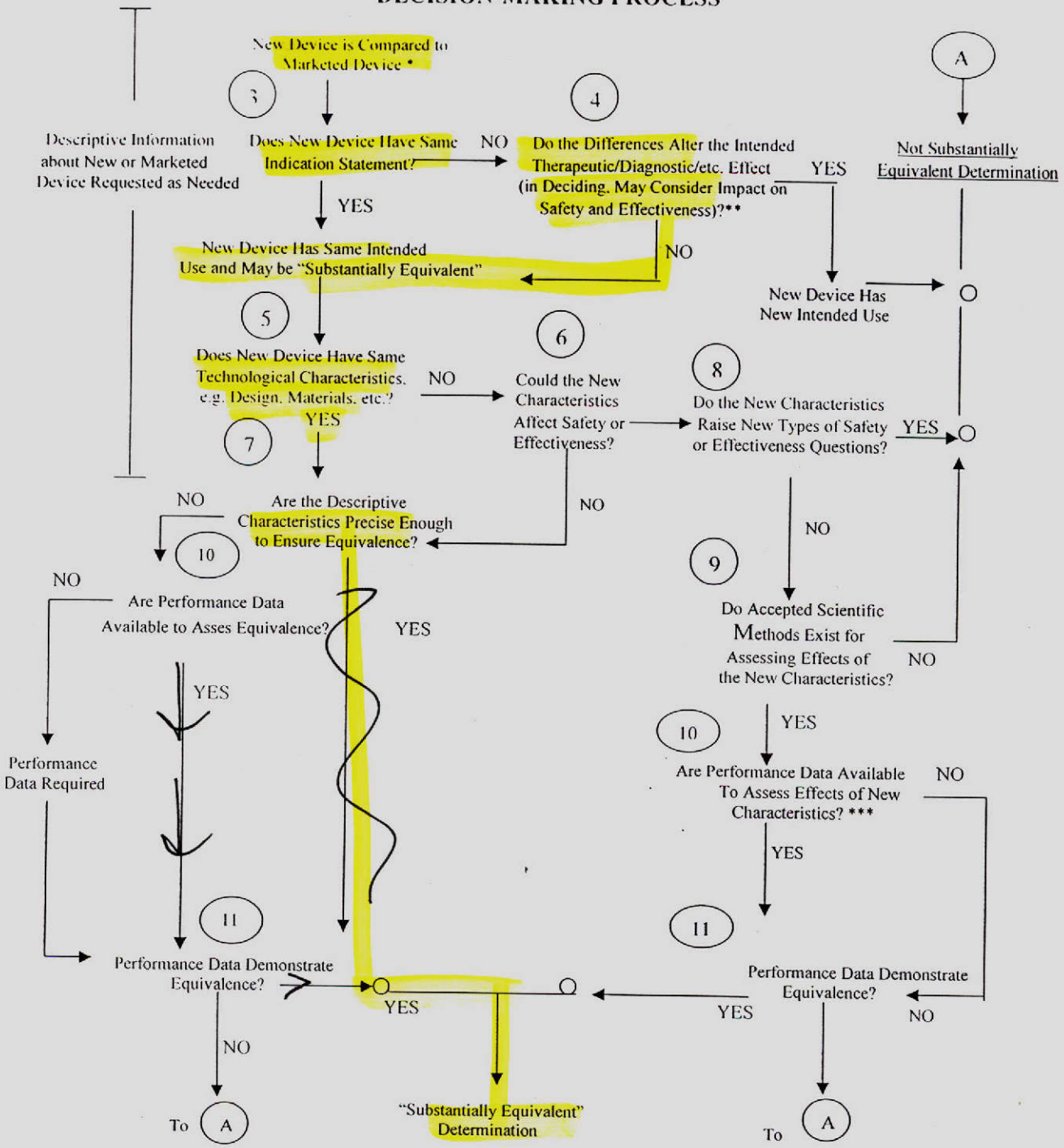
Administrative Requirements:

Truth and Accurate Statement- page 1
Indication for Use- page 3
510 (k) Summary- pages 21-23

Summary: The device is SE to the predicates.

Herbert Lerner, MD

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K K033671

Reviewer: Herbert Lerner MD

Division/Branch: ODE / DGRD / PRSB

Device Name: Bioabsorbable Mesh

Product To Which Compared (510(K) Number If Known): _____

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?		✓	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		✓	If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		✓	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?	✓		If NO = Request Data
11. Data Demonstrate Equivalence?	✓		Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough: Differences in manufacturing methods and design specifications

8. Explain new types of safety or effectiveness questions raised or why th questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		