SEP 17 2003

K031925 (p. 1 of 2)

SECTION 8

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

NEW DEVICE NAME: PROCEED* Surgical Mesh

PREDICATE DEVICES NAME: PROLENE Soft Polypropylene Mesh.

Device Description

PROCEED* Surgical Mesh is a sterile mesh designed for the repair of hernias and other fascial deficiencies. The mesh product has separate layers comprising of PROLENE* Soft Mesh, a nonabsorbable polypropylene mesh, a fabric of oxidized regenerated cellulose (ORC) and a polydioxanone polymer film.

Intended Use

PROCEED Mesh may be used for the repair of hernias and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Indications Statement

PROCEED Mesh may be used for the repair of hernias and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

K031925 (p. 2 of 2)

Technological Characteristics

PROCEED has similar technological characteristics as the predicate devices. The addition of another layer to the standard base surgical mesh material is common to the W.L. GORE & Associates, Inc. DualMesh** Biomaterial (K963619), the Genzyme Corp. Sepramesh** Biosurgical Composite (K994328) and the Bard Composix** Mesh (510K K971745) with a performance characteristic of minimizing tissue attachment to the base mesh material. With the addition of the ORC layer to minimize tissue attachment to the base PROLENE Soft Mesh, the PROCEED Mesh continues to meet the functional requirements of a surgical mesh

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Performance Data

Non-clinical laboratory testing was performed demonstrating that the device is comparable to standard surgical mesh devices that are indicated for hernia repair and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain that desired surgical result. Additionally, in-vivo testing was provided showing that the device performed as intended and as claimed.

Conclusions

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the modified device is substantially equivalent to the Predicate Devices under the Federal Food, Drug, and Cosmetic Act.

Contact

Rey Librojo
Senior Project Manager, Regulatory Affairs
ETHICON Products
ETHICON, Inc.
Rt. #22, West
Somerville, NJ 08876-0151

Date

September 3, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2003

Mr. Rey Librojo
Senior Project Manager, Regulatory Affairs
Ethicon, Inc.
Rt. #22 West
Somerville, New Jersey 08876-0151

Re: K031925
Trade/Device Name: PROCEED* Trilaminate Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Polymeric surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: June 20, 2003
Received: June 27, 2003

Dear Mr. Librojo:

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,

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

INDICATIONS FOR USE

510(k) Number (if known): K031925

Device Name: PROCEED* Trilaminate Surgical Mesh

Indications for Use: PROCEED Mesh may be used for the repair of hernias and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-9G)

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

510(k) Number K031925

* Trademark