SUMMARY OF SAFETY AND EFFECTIVENESS

DEC 1 2 2002

I. GENERAL INFORMATION

A. Submitted By:

Center for Biomaterials and Advanced Technologies, Medical Devices Group, a division of Ethicon, Inc.
Route 22 West, P.O. Box 151
Somerville, NJ 08876

Tel: (908) 218-2041
Fax: (908) 218-3679

Contact Person: David A. Dalessandro
At address above

B. Device Trade Name: Reinforced Absorbable Synthetic Surgical Mesh
Common Name: Surgical Mesh
Classification Name: Mesh, Surgical, Polymeric
FTL, 21 CFR 878.3300

C. Predicate Device(s):

Manufacturer	Product Name	510(k) No.
Ethicon, Inc.	PDS™ (polydioxanone) Mesh	K844228
J&J Corporate Biomaterials Center	AFB (Absorbable Foam Buttress)	K014183

D. Device Description:

The reinforced absorbable synthetic surgical mesh is a foam encased mesh. The foam component is a biocompatible elastomeric polymer that is bioabsorbable. This elastomer exhibits a high percent elongation, while possessing good tensile strength and good recovery characteristics. It has been found to be non-antigenic, non-pyrogenic, and elicits a slight, but typical, tissue reaction during absorption. Therapeutically, the foam component provides wound support as well as increases the opportunity for bridging to occur due to its porosity. The mesh component is a woven polydioxanone mesh that is used to provide wound support during the healing process. It has been found to be non-antigenic, non-pyrogenic, and also elicits a slight, but typical, tissue reaction during absorption. Therapeutically, the mesh component retains strength for a period of time long enough to permit sufficient healing, preventing wound dehiscence.

Accordingly, no or minimal undesirable side effects occur during the healing process.

E. Indications for Use:

Reinforced Absorbable Synthetic Surgical Mesh is indicated for use in the surgical repair of damaged or ruptured soft tissue where reinforcing or bridging materials are needed. This device is intended for one-time use.

F. Technological Comparison:

The reinforced absorbable synthetic surgical mesh and PDS™ Mesh (K844228) have similar indications for use and overall function and perform in a similar manner with respect to reinforcement of soft tissue wound strength. The reinforced absorbable synthetic surgical mesh has similar absorption, degradation, and burst strength to the predicate device.

The foam component of the reinforced absorbable synthetic surgical mesh functions and performs in the same manner as AFB (Absorbable Foam Buttress) (K014183).

II. TESTING

The biocompatibility testing for AFB and PDS™ Mesh are sufficient and applicable to the reinforced absorbable synthetic surgical mesh. Accordingly, no additional biocompatibility or animal testing on the reinforced absorbable synthetic surgical mesh was performed.

III. CONCLUSIONS

In summary, Center for Biomaterials and Advanced Technologies, Medical Devices Group, a division of Ethicon, Inc. has demonstrated that the intended use for the reinforced absorbable synthetic surgical mesh is the same as the original devices. The technological characteristics have been described in sufficient detail to demonstrate that they are the same as the original devices. Therefore, this premarket notification has demonstrated substantial equivalence as defined and understood in the Federal Food, Drug, & Cosmetic Act and its amendments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2 2002

Center for Biomaterials and Advanced Technologies
Melissa Mahall
c/o Bio-Reg Associates
11800 Baltimore Avenue, Suite 105
Beltsville, Maryland 20705

Re: K023328
Trade/Device Name: Reinforced Absorbable Synthetic Surgical Mesh
Regulation Number: 878.3300
Regulation Name: Polymeric Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: October 2, 2002
Received: October 4, 2002

Dear Ms. Mahall:

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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K023328

Device Name: Reinforced Absorbable Synthetic Surgical Mesh

Sponsor Name: Center for Biomaterials and Advanced Technologies, Medical Devices Group, a division of Ethicon, Inc.

Indications for Use:

Reinforced Absorbable Synthetic Surgical Mesh is indicated for use in the surgical repair of damaged or ruptured soft tissue where reinforcing or bridging materials are needed. This device is intended for one-time use.

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
Over-The-Counter Use ☐

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

510(k) Number K023328