K061533

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DEC 1 1 2006

Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below.

Submitted by:

Bryan A. Lisa
Sr. Regulatory Affairs Associate
Ethicon, Inc., A *Johnson & Johnson* Company
Route 22 West, PO Box 151
Somerville, NJ 08876

Name/Classification of Device:

Class II in 21 CFR § 878.3300, Surgical Mesh (FTL)

Trade Name:

PROCEED* Ventral Patch

Predicate Devices:

PROLENE* Soft Mesh
PROCEED* Mesh
BARD Ventralex & Small Ventralex Hernia Patch
VICRYL* Mesh
ETHIBOND* Polyester Suture

Statement of Intended Use:

PROCEED Ventral Patch is intended for the repair of hernias or other abdominal fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

PROCEED Ventral Patch is also indicated for the repair of tissue deficiencies caused by trocar use.

Device Description:

The proposed PROCEED Ventral Patch (PVP) is a self-expanding, partially absorbable, laminate mesh device that is designed for the repair of hernias and other fascial deficiencies such as those caused by trocar use. The mesh device is comprised of several layers: an absorbable fabric of oxidized regenerated cellulose (ORC), PROLENE* Soft Mesh, two absorbable polydioxanone polymer rings, VICRYL* Mesh, polydioxanone polymer film, and polyester suture.

Summary of Technological Characteristics of New Device to Predicate Devices:

The modified device has similar technological characteristics as the predicate devices. Like currently marketed devices, it is a sterile, mesh implant intended for the repair of hernias or abdominal fascial defects. Like several

of the currently marketed devices, the proposed device is made of nonabsorbable and absorbable polymers. The polymers used are identical to those found in PROCEED Mesh and VICRYL Mesh, currently marketed by Ethicon, Inc.

Performance Data:

Biological reactivity of the materials has been assessed using methods specified in ISO Standard 10993-1, and the material was found to be acceptable for its intended use. Results of functional performance testing (bench and animal testing) indicate that the proposed device meets or exceeds all functional requirements.

Conclusions:

Based on the similarities to the predicate devices identified in this submission, we conclude that the modified device is substantially equivalent to the predicate devices under the Federal Food, Drug, and Cosmetic Act.

** Trademark of Ethicon, Inc.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ethicon, Inc.
% Mr. Bryan A. Lisa
Senior Regulatory Affairs Associate
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876

DEC 1 1 2006

Re: K061533
Trade/Device Name: PROCEED* Ventral Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: November 21, 2006
Received: November 22, 2006

Dear Mr. Lisa:

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): K061533

Device Name: PROCEED* Ventral Patch

Indications for Use:

PROCEED Ventral Patch is intended for the repair of hernias or other abdominal fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

PROCEED Ventral Patch is also indicated for the repair of tissue deficiencies caused by trocar use.

*Trademark.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061533