MAY 25 2006

K060713
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SECTION 5 – 510(K) SUMMARY

510(k) Summary	
Submitter	Ethicon Inc., a Johnson and Johnson Company
Contact Information	Sergio J. Gadaleta, Ph.D. Director, Worldwide Regulatory Affairs Ethicon Inc., a Johnson & Johnson Company P.O. Box 151 Route 22 West Somerville, NJ 08876 Telephone: 908-218-3102 Facsimile: 908-218-2595 e-mail: sgadale@ethus.jnj.com
Date	March 10, 2006
Trade Name	PROCEED Surgical Mesh
Common Name	Surgical Mesh
Classification Name	Surgical Mesh Regulation Number: 878.3300 Product Code: FTL
Predicate Device	PROCEED Trilaminate Surgical Mesh
Device Description	PROCEED Surgical Mesh is a sterile, thin, flexible laminate mesh deigned for the repair of hernias and other fascial deficiencies. The mesh product is comprised of an oxidized regenerated cellulose (ORC) fabric, and PROLENE* Soft Mesh, a nonabsorbable polypropylene mesh, which is encapsulated by a polydioxanone polymer. The polypropylene

	mesh side of the product allows for tissue ingrowth while the ORC side provides a bioresorbable layer that physically separates the polypropylene mesh from underlying tissue and organ surfaces during the wound-healing period to minimize tissue attachment to the mesh. The polydioxanone provides a bond to the ORC layer.
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.
Technological Characteristics	The technological characteristics of PROCEED Surgical Mesh are identical to the predicate device, PROCEED SURGICAL Mesh.
Conclusions	The descriptive information provided about PROCEED Surgical Mesh demonstrates substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2006

Ethicon Inc., a Johnson & Johnson Co.
% Sergio J. Gadaleta, Ph.D.
Director, Worldwide Regulatory Affairs
Route 22 West, P.O. Box 151
Somerville, NJ 08876

Re: K060713
Trade/Device Name: PROCEED Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: May 10, 2006
Received: May 11, 2006

Dear Dr. Gadaleta:

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.

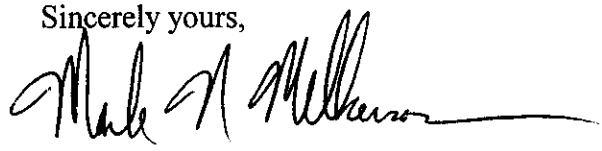
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

SECTION 4 – INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K060713
Device Name: PROCEED Surgical Mesh
Indications for Use:

PROCEED Surgical 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.

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 K060713