JUN - 5 2007

PMN-2007-001

K071249

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:

Patrice Napoda
Manager Regulatory Affairs
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:

ULTRAPRO* Hernia System

Predicate Devices:

PROLENE* Hernia System
ULTRAPRO* Mesh

Statement of Intended Use:

The ULTRAPRO* Hernia System is intended for use in open repairs of abdominal wall hernia defects.

Device Description:

The proposed ULTRAPRO* Hernia System (UHS) is a sterile, pre-shaped, three-dimensional device constructed of an undyed onlay patch connected by a mesh cylinder to an underlay patch which is reinforced by a flat undyed absorbable film of Poliglecaprone-25 (MONOCRYL*). The underlay patch is marked with dyed polypropylene fibers to be clearly distinguishable from the onlay patch. The onlay patch, connector and underlay patch are manufactured from approximately equal parts of absorbable Poliglecaprone-25 monofilament fiber and non-absorbable polypropylene monofilament fiber. The polymer of the undyed and dyed polypropylene fibers (phthalocyanine blue, Color Index No. 74160) is identical to the material used for dyed/undyed PROLENE* suture material. Poliglecaprone-25 fiber consists of a copolymer containing glycolide and ϵ-caprolactone. This copolymer is also used for MONOCRYL* suture material. After absorption of the Poliglecaprone-25 components only the polypropylene mesh remains. The structure and size of this remaining mesh are designed for the physiological stresses to which the abdominal wall is subject. The UHS is available in different sizes.

Summary of Technological Characteristics of New Device to Predicate Devices:

The modified device has similar technological characteristics to those of the predicate devices. Like the currently marketed PROLENE Hernia System, the ULTRAPRO Hernia System is a sterile, pre-shaped three-dimensional device constructed of an onlay patch connected by a mesh cylinder to an oval or circular underlay patch. The ULTRAPRO Hernia System is composed of approximately equal parts of absorbable poliglecaprone-25 monofilament fiber and non-absorbable polypropylene monofilament fiber, a material identical to the currently marketed ULTRAPRO Mesh. After absorption of the poliglecaprone-25 materials, the remaining polypropylene mesh provides the long-term tissue support, similar to the PROLENE Hernia System.

Performance Data:

Biological reactivity of the materials has been assessed using methods specified in ISO Standard 10993-1, with results demonstrating that the materials are acceptable for the 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 device, 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
% Ms. Patrice Napoda
Manager, Regulatory Affairs
PO Box 151, Route 22 West
Somerville, New Jersey 08876

JUN - 5 2007

Re: K071249
Trade/Device Name: ULTRAPRO* Hernia System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: May 03, 2007
Received: May 04, 2007

Dear Ms. Napoda:

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,

For Director DGP 6/15/07

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): _____

Device Name: ULTRAPRO* Hernia System

Indications for Use:

This product is indicated for open repair of abdominal wall hernia defects.

*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 K071249