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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

APR 17 2007

Name/Classification of Device:

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

Trade Name:

ULTRAPRO* Plug

Predicate Devices:

ULTRAPRO* Mesh (ETHICON, Inc.) – K033337
BARD Mesh PerFix Plug (Davol, Inc.) – K922916

Statement of Intended Use:

ULTRAPRO Plug is a partially absorbable device used to fill and reinforce inguinal hernia defects. ULTRAPRO Plug is indicated for open repair of groin hernia defects.

Device Description:

The ULTRAPRO Plug device is composed of two sterile components: a thermoformed, three-dimensional plug and a flat, preshaped onlay patch. The ULTRAPRO Plug device is indicated for the open repair of groin hernia defects.

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 hernia defects. **The proposed device is made of nonabsorbable and absorbable polymers, which are identical to those found in ULTRAPRO Mesh, currently marketed by ETHICON, Inc.**

Performance Data:

Biological reactivity of the materials has been assessed using methods specified in ISO 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.

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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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

APR 17 2007

Re: K070224
Trade/Device Name: ULTRAPRO* Plug
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: April 6, 2007
Received: April 9, 2007

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.

Page 2 – Mr. Bryan A. Lisa

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 Peter Rumm
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DEP Dir
4/14/07

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): K070224

Device Name: ULTRAPRO* Plug

Indications for Use:

ULTRAPRO Plug is indicated for open repair of groin hernia defects.



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

*Trademark.

510(k) Number L070224

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