

K972412

SEP 10 1997

SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

**510(k) 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. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

NEW DEVICE NAME: ETHICON PROLENE\* Polypropylene Mesh Hernia Device Nonabsorbable Synthetic Surgical Mesh Implant

PREDICATE DEVICE NAME: BARD® Marlex® Mesh PerFix® Plug Nonabsorbable Polypropylene Surgical Mesh Device

510(k) SUMMARY

**Device Description**

The PROLENE Polypropylene Mesh Hernia Device is a sterile, pre-shaped, three dimensional device constructed of an onlay patch connected by a mesh cylinder to a circular underlay patch. The material is undyed PROLENE\* polypropylene mesh constructed of knitted non-absorbable polypropylene filaments identical to that used in PROLENE\* polypropylene nonabsorbable surgical sutures, U.S.P. (ETHICON, INC.). This material, when used as a suture, has been reported to be nonreactive and to retain its strength indefinitely in clinical use.

**Intended Use**

The PROLENE Mesh Hernia Device is intended to be used for the repair of indirect and direct inguinal hernia defects..

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\* Trademark

PROLENE Polypropylene Mesh Hernia Device  
ETHICON, Inc.

SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

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510(k) SUMMARY, Continued

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**Indications Statement**

The PROLENE Mesh Hernia Device is indicated for the repair of inguinal hernia defects, both indirect and direct.

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**Technological Characteristics**

The modified device has comparable technological characteristics to the predicate device. Both devices are pre-shaped, three dimensional devices constructed of knitted polypropylene monofilaments.

When compared to the predicate device, the PROLENE Mesh Hernia Device is a single device which requires no sutures to secure into place. The PerFix Plug is available as two separate pieces in which the fluted mesh must be sutured into place.

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**Performance Data**

ETHICON, Inc has conducted a preclinical study to show that the PROLENE Mesh Hernia Device is effective in repairing inguinal hernias, maintaining its position in the inguinal canal without the aid of sutures. Postoperative tissue ingrowth and functionality were demonstrated.

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**Conclusions**

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the modified device is substantially equivalent to the Predicate Device under the Federal Food, Drug, and Cosmetic Act.

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\* Trademark

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PROLENE Polypropylene Mesh Hernia Device  
ETHICON, Inc.

SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

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**Contact** Gregory R. Jones  
Director, Regulatory Affairs  
ETHICON, Inc.  
Rt. #22, West  
Somerville, NJ 08876-0151

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**Date** June 25, 1997

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PROLENE Polypropylene Mesh Hernia Device  
ETHICON, Inc.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 10 1997

Mr. Gregory R. Jones  
Director, Regulatory Affairs  
ETHICON, Inc.  
PO Box 151  
Somerville, New Jersey 08876-0151

Re: K972412  
Trade Name: PROLENE Polypropylene Mesh Hernia Device  
Regulatory Class: II  
Product Code: FTL  
Dated: June 25, 1997  
Received: June 26, 1997

Dear Mr. Jones:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

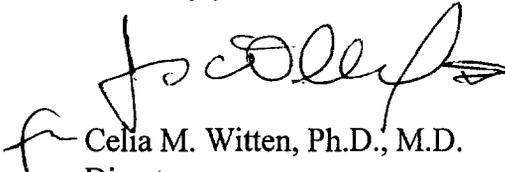
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Gregory R. Jones

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K972412

**INDICATIONS FOR USE**

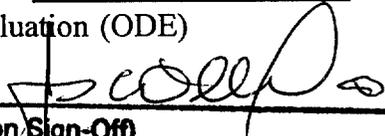
510(k) Number (if known): \_\_\_\_\_

Device Name: PROLENE Polypropylene Mesh Hernia Device

Indications for Use: The PROLENE Polypropylene Mesh Hernia Device is indicated for the repair of indirect and direct inguinal hernia defects.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K972412

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The Counter Use \_\_\_\_\_

(Optional Format 1-2-9G)