K002672

NOV 22 2000

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.

MODIFIED DEVICE NAME: VYPRO* Mesh

PREDICATE DEVICE NAME: PROLENE* (Polypropylene) Mesh and VICRYL* (Polyglactin 910) Mesh for materials and indications and MERSILENE* Polyester Mesh for Indications For Use.

510(k) SUMMARY

Device Description

VYPRO Mesh is constructed from approximately equal parts of absorbable polyglactin 910 multifilament fiber and non-absorbable polypropylene multifilament fiber. The purpose of the absorbable polyglactin component is to add firmness to the polypropylene structure and thus make intraoperative handling of the mesh easier. The mesh affords excellent strength, durability and surgical adaptability, with a porous structure to enable mesh incorporation into surrounding tissues. The polymer of the polypropylene fiber is identical to that used in PROLENE* Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use.

Continued on next page

510(k) SUMMARY, Continued

Description (continued)

The polyglactin fiber consists of a copolymer containing 90% glycolide and 10% lactide. This copolymer is identical in composition to that used in VICRYL* (polyglactin 910) synthetic absorbable suture, which has been found to be nonantigenic, nonpyrogenic and to elicit only a mild tissue reaction during absorption. The polyglactin component is absorbed within 56 to 70 days, leaving the permanent polypropylene mesh structure that is designed for the physiological stresses to which the abdominal wall is subject.

Intended Use

This mesh is intended for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Indications Statement

This mesh is used for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Technological Characteristics

The technological characteristics that were evaluated for VYPRO Mesh include: thickness, burst strength, flexural rigidity, tear strength, suture pull-out and tensile strength. The values established for VYPRO Mesh are less than those for PROLENE Mesh, but greater than MERSILENE Mesh. VYPRO Mesh has a larger pore size, flexibility and thickness than PROLENE Mesh, but maintains a higher burst strength than MERSILENE Mesh.

Performance Data

Nonclinical laboratory testing was not performed as there is no change to the clinical intended use as compared to the predicate devices. Sufficient bench testing was conducted in accordance with the FDA guidance document “”Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh.”

Continued on next page

K002672

SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

Performance Data (continued)	The results of a clinical study compared the use of VYPRO Mesh with MARLEX and ATRIUM Meshes. This study has found VYPRO Mesh to be acceptable with regard to mechanical and healing characteristics including some advantages in bench testing and clinical trials.
Conclusions	Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug, and Cosmetic Act.
Contact	Gregory R. Jones Director, Regulatory Affairs ETHICON, Inc. Rt. #22, West Somerville, NJ 08876-0151
Date	August 25, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2000

Mr. Gregory R. Jones
Director, Regulatory Affairs
Ethicon, Inc.
Route 22 West
P.O. Box 151
Somerville, New Jersey 08876

Re: K002672
Trade Name: VYPRO Mesh VICRYL-PROLENE Partially Absorbable Synthetic Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: August 25, 2000
Received: August 28, 2000

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 requirement, 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.

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,

for Mark N Melkerson

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

Enclosure

K002672

INDICATION FOR USE

510(k) Number (if known): _____

Device Name: VYPRO* Mesh VICRYL*-PROLENE* Partially Absorbable Synthetic Surgical Mesh

Indications for Use: VYPRO Mesh is indicated for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

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

_____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use _____
(Per 21 CFR 801.109)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002672

(Optional Format 1-2-9G)