MAY 23 2000

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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: PROLENE Soft* (Polypropylene) Mesh

PREDICATE DEVICE NAME: PROLENE* (Polypropylene) Mesh and MERSILENE* Mesh

510(k) SUMMARY

Device Description

PROLENE Soft* polypropylene mesh is constructed of knitted filaments of extruded polypropylene identical in composition to that used in PROLENE* Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). The mesh affords excellent strength, durability and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE mesh. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use.

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510(k) SUMMARY, Continued

Description (continued)

PROLENE Soft mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaption to various stresses encountered in the body.

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

For technological characteristics, the values established for PROLENE Soft mesh are less than those of PROLENE mesh, but greater than those of MERSILENE mesh. Both PROLENE Soft mesh and PROLENE mesh are constructed of polypropylene fibers. PROLENE Soft mesh offers a 50% more flexible monofilament mesh.

Performance Data

Nonclinical laboratory testing was not performed as there is no change to the clinical intended use as compared to the two 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.”

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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 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

April 6, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2000

Mr. Gregory R. Jones
Director, Regulatory Affairs
Ethicon, Inc.
Route 22
Somerville, New Jersey 08876

Re: K001122
Trade Name: PROLENE Soft (Polypropylene) Mesh
Regulatory Class: II
Product Code: FTL
Dated: April 6, 2000
Received: April 7, 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,

Donna R. Lochner

for 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

INDICATION FOR USE

510(k) Number (if known): K001122

Device Name: PROLENE Soft* (Polypropylene) Mesh.

Indications for Use: The PROLENE Soft (Polypropylene) 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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001122

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

(Optional Format 1-2-9G)