2/23/99

K984220

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* (Polypropylene) Hernia System

PREDICATE DEVICE NAME: PROLENE* (Polypropylene) Hernia System

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510(k) SUMMARY

Device Description

The PROLENE Hernia System is a sterile, pre-shaped three dimensional device constructed of an onlay patch connected by a cylinder to a circular or oblong 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 Hernia System is intended to be used for the repair of abdominal wall hernia defects.

Continued on next page

SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

510(k) SUMMARY, Continued

Indications Statement	The PROLENE Hernia System is indicated for the repair of abdominal wall hernia defects.
Technological Characteristics	The modified device has identical technological characteristics to the predicate device.
Performance Data	Nonclinical laboratory testing was not performed.
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	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 1999

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

Re: K984220
Trade Name: PROLENE* (Polypropylene) HERNIA SYSTEM
Regulatory Class: II
Product Code: FTL
Dated: November 24, 1998
Received: November 25, 1998

Dear Mr. Jones:

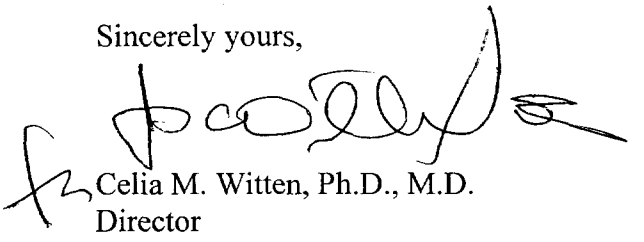
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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

K984220

INDICATION FOR USE

510(k) Number (if known): K984220

Device Name: PROLENE* (Polypropylene) HERNIA SYSTEM.

Indications for Use: The PROLENE (Polypropylene) Hernia System is indicated for the repair of abdominal wall hernia defects.

(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)

(Optional Format 1-2-9G)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984220