K053414/2

DEC 2 7 2005

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: _____

Contact Person: Donna A. Crawford
Director, Domestic Regulatory Submissions
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA 93111

Telephone: 805-879-6304
FAX: 805-879-6015

Date Prepared: December 2, 2005

Device Name and Classification

Proprietary Name:	Mentor NovaSilk™ Mesh
Common Name:	Surgical Mesh
Classification Name:	Surgical Mesh, polymeric
Class:	Class II
Product Code:	OTP, PAI, OTO, PAJ
CFR #:	§878.3300

Device Description

NovaSilk is a permanent, synthetic knitted polypropylene mesh that is square in shape. It is a sterile, single use device which will be available in quantities of three.

Substantial Equivalence Claim

The Mentor NovaSilk Mesh is substantially equivalent in material, function, performance and design to the Gynemesh Prolene Soft (Polypropylene) Mesh that was cleared under 510(k) K013718. Knitted polypropylene is currently used in Mentor's Aris Sling which was cleared under 510(k) K050148.

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Indications for Use

The Mentor NovaSilk Mesh is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Summary of Testing

The following characteristics were assessed for NovaSilk: overall product dimensions, including fiber and pore sizes; density and porosity; burst and tear strength; tensile strength and elongation; stiffness; suture pull strength; and edge integrity and curling.

The following biocompatibility testing was performed on NovaSilk: pyrogenicity, cytotoxicity and acute systemic toxicity. NovaSilk has been demonstrated to be nontoxic and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Donna A. Crawford
Director, Domestic Regulatory Submissions
Mentor Corporation
201 Mentor Drive
SANTA BARBARA CA 93111

SEP 28 2012

Re: K053414
Trade/Device Name: Mentor NovaSilk Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTP, PAI, OTO, PAJ
Dated: December 2, 2005
Received: December 7, 2005

Dear Ms. Crawford:

This letter corrects our substantially equivalent letter of December 27, 2005.

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 (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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K053414

510(k) Number (if known): ____ _____

Device Name: Mentor NovaSilk™ Mesh

Indications for Use:

The Mentor NovaSilk Mesh is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ann MD

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

510(k) Number K053414