K980483

MENTOR CORPORATION
Executive Offices
5425 Hollister Avenue Santa Barbara, CA 93111 (805) 681-6000

APR 30 1998

510(k) SUMMARY
MENTOR SUSPEND™ SLING

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: K980483

Submitter/
Contact Person: Donna A. Crawford
Manager, Corporate Regulatory Affairs
Mentor Corporation
5425 Hollister Ave.
Santa Barbara, CA 93111

Telephone: (805) 681-6000
FAX: (805) 681-6004

Date Prepared: April 21, 1998

Device Name and Classification

Proprietary Name:	Mentor SUSPEND™ Sling
Common Name:	Sling
Classification Name:	Surgical mesh, polymeric
Classification:	Class II per 21 CFR 878.3300

Manufacturer

Mentor Urology
601 West River Road North
Minneapolis, MN 55411

Substantial Equivalence Claim

The Mentor SUSPEND™ Sling is substantially equivalent to the GoreTex™ Tissue Reinforcement Patch and the ProteGen™ Sling.

Indications For Use

The Mentor SUSPEND™ Sling is an implant which is intended to reinforce soft tissue where weakness exists in the urological anatomy inclusive of the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, reconstruction of the pelvic floor, and sacro-colposuspension. It is intended for the treatment of female urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

Device Description

The Mentor SUSPEND™ Sling is rectangular in shape and will be made available in several sizes: 2 cm x 4 cm, 3 cm x 5 cm, and 4 cm x 7 cm to accomodate various patient profiles. An aperature matrix is incorporated throughout the device. The Mentor SUSPEND™ Sling is manufactured from a biocompatible, segmented polyether urea urethane elastomer. An anti-bacterial coating has been incorporated onto the surface of the device.

Summary of Testing

The material used in the Mentor SUSPEND™ Sling has been tested for biocompatibility and passed all tests.

The Mentor SUSPEND™ Sling was tested for suture pull strength to determine the point at which the suture would "tear" the sling. The test results showed that the Mentor SUSPEND™ Sling met the design criteria for suture pull strength.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1998

Ms. Donna A. Crawford
Manager, Corporate Regulatory Affairs
Mentor Corporation
Executive Offices
5425 Hollister Avenue
Santa Barbara, California 93111

Re: K980483
Trade Name: Mentor Suspend Sling
Regulatory Class: II
Product Code: FTL
Dated: February 6, 1998
Received: February 9, 1998

Dear Ms. Crawford:

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 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

510(k) Number (if known): K980483

Device Name: MENTOR SUSPEND™ Sling

Indications For Use:

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(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 K980483

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

(Optional Format 1-2-96)