AUG 2 8 2002

III. Summary of Safety and Effectiveness

K021834

510(k) Summary for Suture Fixation System

A. Sponsor

MLE, Inc.
52 Commercial Wharf #1
Boston, MA 02110

B. Device Name

Suture/ Mesh Fixation System

C. Predicate Device(s)

21CFR 878.4930 Class I, KGS Suture retention device
Devices Classified per 21CFR 878.5010 as Class II, procode GAW
MBI, Soft tissue Fastener

D. Device Description

The system includes a surgical stainless steel retention anchor with attached polypropylene suture, and a delivery device for placement of the implant. The system may be supplied with legally marketed surgical mesh marketed for use in treating female stress urinary incontinence.

1) Intended Use

For use in procedures requiring fixation of suspending sutures and/or surgical mesh to soft tissue. This includes but is not limited to pubourethral support and bladder neck support procedures for the treatment of female stress urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency.

2) Technological Characteristics and Substantial Equivalence

The proposed device is substantially equivalent to the predicate devices currently marketed for use for fixation of soft tissue in terms of intended use and functional characteristics tested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2002

MLE, Inc.
c/o Ms. Christine E. Nichols
RCS Regulatory Consulting Services
10 Greenlawn Avenue
S. Grafton, Massachusetts 01560

Re: K021834
Trade/Device Name: Suture Fixation Device and Mesh Fixation Device
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable Polypropylene Surgical Suture
Regulatory Class: Class II
Product Code: GAW
Dated: May 29, 2002
Received: June 4, 2002

Dear Ms. Nichols:

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 application (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.

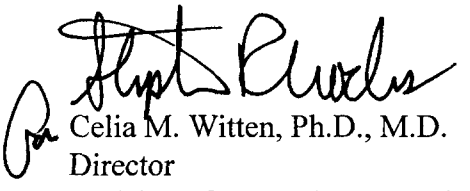
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html .

Sincerely yours,



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

IV. Indications for Use Statement

510(k) Number (if Known): K021834

Device Name: Suture/Mesh Fixation System

Indications For Use:

For use in procedures requiring fixation of suspending sutures and/or surgical mesh to soft tissue. This includes but is not limited to pubourethral support and bladder neck support procedures for the treatment of female stress urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Optional Format 1-2-96)

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

510(k) Number K021834