NOV 2 9 2000

510(k) Summary
AMS Triangle™ Silicone-Coated Sling and Surgical Mesh
510(k) Number K002721

Submitter/Contact Person:

Ginger Sackett Glaser
Sr. Regulatory Affairs Specialist
American Medical Systems
10700 Bren Rd. W
Minnetonka, MN 55343

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Device Name and Classification:

Trade Name: AMS Triangle™ Silicone-Coated Sling and Surgical Mesh
Common/Usual Name: Surgical Mesh, Sling, Urethral Sling
Classification Name: Surgical Mesh, polymeric
Product Code: FTL
Classification: Class II

Manufacturing Location:

American Medical Systems, Inc.
10700 Bren Rd. West
Minnetonka, MN 55343

Predicate Devices:

TriAngle™ Sling - K980482
Bard® Marlex Mesh - K922916
Ethicon™ Prolene™ Mesh - K962530
Mersilene™ Mesh
Mentor SUSPEND™ Sling - K980483

Indications for Use:

The AMS Triangle™ Silicone-Coated Sling and Surgical Mesh is an implant that is intended for the treatment of urinary incontinence resulting from urethral hypermobility or ISD and for implantation to reinforce soft tissues where weakness exists in the urological, gynecological or gastroenterological anatomy. This includes, but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral-colposuspension.

Device Description:

The AMS Triangle™ Silicone-Coated Sling and Surgical Mesh is made of a polyester mesh that is covered with a thin layer of solid silicone elastomer. The AMS Triangle™ Silicone-Coated Sling and Surgical Mesh is available in sizes ranging from 10 cm^2 to 144 cm^2, including 2 cm x 5 cm, 2 cm x 4 cm, 2 cm x 10 cm, 2 cm x 7 cm, 2 cm x 20 cm, 6 cm x 6cm and 12 cm x 12cm.

Summary of Testing

The material used in the AMS Triangle™ Silicone-Coated Sling and Surgical Mesh has been demonstrated to be biocompatible.

The AMS Triangle™ Silicone-Coated Sling and Surgical Mesh has been tested for a variety of physical characteristics including tensile strength and suture pull strength and has been shown to be equivalent to the listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2000

Ms. Ginger S. Glaser
Sr. Regulatory Affairs Specialist
American Medical Systems
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K002721
Trade Name: AMS Triangle Silicone-Coated Sling and Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: August 24, 2000
Received: August 31, 2000

Dear Ms. Glaser:

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 Mark N. Melkerson

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

K002721

510(k) Number (if known):_____

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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)

(Optional Format 3-10-98)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002721