



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

Ms. Elsa A. Linke
Regulatory Affairs
American Medical Systems, Inc.
10700 Bren Road West
MINNETONKA MN 55343

SEP 28 2012

Re: K010931
Trade/Device Name: AMS Silicone-Coated Sling and Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTO
Dated: March 27, 2001
Received: March 28, 2001

Dear Ms. Linke:

This letter corrects our substantially equivalent letter of April 9, 2001.

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.

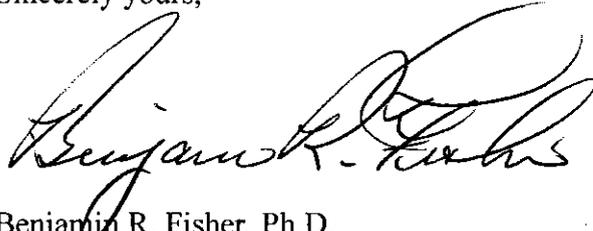
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher". The signature is fluid and cursive, with a large initial "B" and "F".

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

INDICATIONS FOR USE ENCLOSURE

510(k) Number: K010931

Device Name: AMS Silicone-Coated Sling and Surgical Mesh

Indications for Use: The AMS 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.

 Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010931

(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 and Restorative Devices

510(k) Number _____

Prescription Use ✓
(Per 21 CFR801.109)

OR

Over the Counter Use _____

APR - 9 2001

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510(k) SUMMARY

Submitter's Name: American Medical Systems, Inc.

Address: 10700 Bren Road West
Minnetonka, MN 55343

Tel: 952-933-4666

Fax: 952-930-6157

Contact Person: Elsa A. Linke

Date of Summary Preparation: March 27, 2001

Device Common Name: Surgical Mesh, Sling

Device Trade Name: AMS Sacral Colpopexy Sling

Device Classification Name: Surgical Mesh, polymeric (21 CFR 878.3300)
Classification: Class II
Product Code: FTL

Predicate Device: AMS Silicone-Coated Sling and Surgical Mesh
K002721

Device Description

The AMS Sacral Colpopexy Sling is an alternate version of the AMS Silicone-Coated Sling and Surgical Mesh. The two slings are exactly the same except for the fact that the Sacral Colpopexy Sling is in the shape of a Y.

Indications for Use

The AMS Sacral Colpopexy Sling 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.

Comparison to Predicate Device

The fundamental scientific technology of the device will not change with the proposed alternative configuration of the device. With the exception of adding an adhesive to form the y-bond, the material characteristics of the device remain the same as in the predicate. The addition of a short arm of sling mesh is the only change to the physical characteristics.

[510(k) Summary continued]

Supporting Information

The mechanical properties of the new y-configuration of the sling have been tested on the bench and shown to meet performance specifications. In addition, the bonding material has been demonstrated to be biocompatible.

Conclusion

The proposed modification is equivalent to the predicate with respect to intended use, technological characteristics, and performance characteristics.