

AUG 3 - 2005

**510(k) Summary  
AMS Pelvic Floor Repair System**

**510(k) Number** K051485

**Date of Summary Preparation:**

June 3, 2005

**Submitter/Contact Person:**

Elsa A. Linke  
Regulatory Affairs Specialist  
American Medical Systems  
10700 Bren Rd. W  
Minnetonka, MN 55343

Phone: (952) 930-6000

Fax: (952) 930-6496

**Device Name and Classification:**

Trade Name: AMS Pelvic Floor Repair System

Common/Usual Name: Surgical Mesh

Classification Name: Surgical Mesh, polymeric

Product Code: OTO, OTP

Classification: Class II

**Manufacturing Location:**

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

**Predicate Devices:**

AMS Apogee – K040537

AMS Perigee – K040623

AMS Pre-Connected Apogee, Perigee, & BioArc – K050445

AMS Porcine Dermis – K050445

AMS Sparc Sling System – K021263

AMS Monarc Sling System – K023516

AMS Silicone-Coated Sling and Surgical Mesh – K002721

AMS Large Pore Polypropylene Mesh – K040521

**Indications for Use:**

The AMS Pelvic Floor Repair System is intended for use where the connective tissue has ruptured or for implantation to reinforce soft tissues where weakness exists in the urological, gynecological and gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support, including urethral slings for the treatment of incontinence, vaginal wall prolapse repairs including anterior and posterior wall repairs, vaginal suspension, reconstruction of the pelvic floor and tissue repair.

**Device Description:**

The AMS Pelvic Floor Repair System consists of needles and mesh used to repair the pelvic floor.

**Summary of Testing**

The components of the AMS Pelvic Floor Repair System have been tested for biocompatibility and performance requirements and found to be substantially equivalent to the predicate devices.



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

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

SEP 28 2012

Re: K051485  
Trade/Device Name: AMS Pelvic Floor Repair System  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: II  
Product Code: OTO, OTP  
Dated: June 3, 2005  
Received: June 6, 2005

Dear Ms. Linke:

This letter corrects our substantially equivalent letter of August 3, 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.

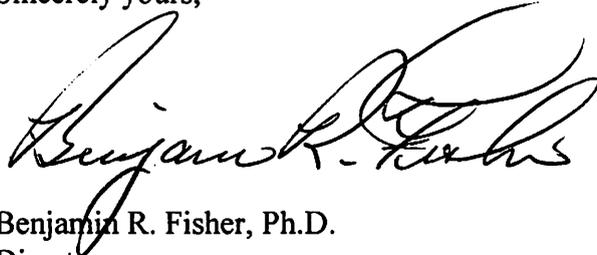
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher". The signature is fluid and cursive, with the first name being the most prominent.

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

510(k) Number (if known):

Device Name: AMS Pelvic Floor Repair System

Indications For Use: The AMS Pelvic Floor Repair System is intended for use where the connective tissue has ruptured or for implantation to reinforce soft tissues where weakness exists in the urological, gynecological and gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support, including urethral slings for the treatment of incontinence, vaginal wall prolapse repairs including anterior and posterior wall repairs, vaginal suspension, reconstruction of the pelvic floor and tissue repair.

Prescription Use  X   
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(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  
and Neurological Devices

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