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K053371

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5. 510(k) Summary Statement

Submitter:	American Medical Systems (AMS) 10070 Bren Road West Minnetonka, MN 55343 Phone: 952.933.4666 FAX: 952.930.6496
Contact Person:	Frank B. Freedman, Ph.D.
Device Common Name:	Sub-Urethral Sling System; Surgical Mesh
Device Trade Name:	AMS Male Transobturator Sling System
Device Classification Name:	Surgical Mesh, polymeric
Predicate Devices:	Short Shaft Straight-In Bone Fixation System (trade name "InVance) (K982155) Monarc Subfascial Hammock (K023516), Sparc Sling System (K011251), Apogee (K040537), Perigee (K040623) and other devices

Device Description
The AMS Male Transobturator Sling System consists of a sling and a surgical instrument (called a "Needle Passer" or Surgical Needle Instrument") for sub-urethral sling placement using a transobturator approach. The slings are made from polymeric mesh and have resorbable sutures.

Indications for Use
The AMS Male Transobturator Sling System is indicated for a sub-urethral sling implant for the treatment of male stress urinary incontinence (SUI).

Comparison to Predicate Devices
The AMS Male Transobturator Sling System provides physicians an alternative surgical approach to implant sub-urethral slings to treat male stress urinary incontinence. The AMS Male Transobturator Sling material, design and characteristics are substantially equivalent to those exhibited by Monarc, Sparc, Apogee, Perigee and other surgical meshes cleared for commercial distribution. The materials, design and characteristics of the AMS Male Transobturator Surgical Needle Instrument (also called "Needle" and "Needle Passer") used for sling placement are substantially equivalent to those embodied in the Monarc Subfascial Hammock Needle Passer and other surgical instruments cleared for commercial distribution.

Supporting Information
Substantial equivalency was supported by previously cleared and new bench and biocompatibility testing, cadaver studies, clinical data and a literature review.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Frank B. Freedman, Ph.D.
Senior Regulatory Affairs Specialist
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K053371
Trade/Device Name: AMS Male TO Sling System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: January 5, 2006
Received: January 6, 2006

Dear Dr. Freedman:

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053371

Device Name: AMS Male TO Sling System

Indications For Use: The AMS Male Transobturator Sling System is indicated for a sub-urethral sling implant to treat male stress urinary incontinence.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Barbara Buchwald for MVM

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

510(k) Number K053371