DEC 14 2004

American Medical Systems

510(k) Summary
AMS InteMesh™ Silicone-Coated Sling and Surgical Mesh with InhibiZone™
510(k) Number K042592

Submitter/Contact Person:
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Sr. Regulatory Affairs Specialist
American Medical Systems
10700 Bren Road West
Minnetonka, MN 55343

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Device Name and Classification:
Trade Name: AMS InteMesh™ Silicone-Coated Sling and Surgical Mesh with InhibiZone™
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 Road West
Minnetonka, MN 55343

Predicate Device:
AMS Triangle™ Silicone-Coated Sling and Surgical Mesh - K002721
Mentor SUSPEND™ Sling – K980483

Indications for Use:
The AMS InteMesh™ Silicone-Coated Sling and Surgical Mesh with InhibiZone™ 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 pubourethral support and bladder support.

Device Description:

The AMS InteMesh™ Silicone-Coated Sling and Surgical Mesh with InhibiZone™ is available in the size 4 cm x 7 cm. This pre-cut piece is specifically sized to support the bladder neck in male perineal sling procedures.

Summary of Testing

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

The AMS InteMesh™ Silicone-Coated Sling and Surgical Mesh with InhibiZone™ 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 device. Testing was also conducted to evaluate the response of tissues to the antibiotics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2004

Ms. Kristyn M. Benson
Senior Regulatory Affairs Specialist
American Medical Systems, Inc.
10700 Bren Road, West
Minnetonka, Minnesota 55343

Re: K042592
Trade/Device Name: InteMesh™ Silicone-Coated Sling and Surgical Mesh with Inhibizone™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: November 11, 2004
Received: November 12, 2004

Dear Ms. Benson:

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" (21CFR 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/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

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

American Medical Systems

INDICATIONS FOR USE STATEMENT

510(k) Number: (Pending)

Device Name: InteMesh™ Silicone-Coated Sling and Surgical Mesh with Inhibizone™

Indications for Use:

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Prescription Use ✓
(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)

Miriam C. Provost

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

510(k) Number K042592