K090934
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510(k) Summary Statement

Submitter:	American Medical Systems (AMS) 10700 Bren Road West Minnetonka, MN 55343
Contact Person:	Sarah J.P. Meyer Phone: 952.930.6431 Fax: 952.930.5785
Device Common Name:	Surgical Mesh
Device Trade Name:	PFR Sling System, Part of the AMS Pelvic Floor Repair System
Device Classification/ Classification Name:	Class II, 21 CFR Part 878.3300 Surgical Mesh, polymeric (FTL)
Predicate Device:	PFR Sling System (K070993), Part of the AMS Pelvic Floor Repair System

JUN - 2 2009

Indications for Use

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 PFR Sling System is a sterile, single use procedure kit that consists of stainless steel, curved needle passers and an implantable mesh assembly.

Summary of Testing

The components of the PFR Sling System have been tested for biocompatibility and performance requirements and found to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2009

American Medical Systems, Incorporation
% Ms. Sarah Meyer
Senior Regulatory Specialist
10700 Bren Road, West
Minnetonka, Minnesota 55343

Re: K090934
Trade/Device Name: PFR Sling System, Part of the AMS Pelvic Floor Repair System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: May 6, 2009
Received: May 7, 2009

Dear Ms. Meyer:

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 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

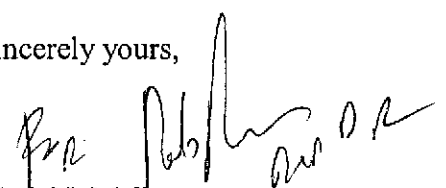
practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ 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" (21CFR 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K090934

Indications for Use Statement

510(k) Number: (if known)	K090934
Device Name:	PFR Sling System, Part of the AMS Pelvic Floor Repair System
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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 IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices