APR - 2 2009

K090713
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2.6 510(k) Summary

Submitter:	American Medical Systems 10700 Bren Road West Minnetonka, MN 55343 Phone: 952-933-4666 Fax: 952-930-6496
Contact Person:	Denise Thompson
Date Summary Prepared:	March 17, 2009
Device Common Name:	Surgical Mesh
Device Trade Name:	Elevate Prolapse Repair System with PC Coated IntePro Lite
Device Classification Name:	Surgical Mesh, polymeric
Predicate Device:	Elevate Prolapse Repair System with IntePro Lite

Device Description
The Elevate System is part of the AMS Pelvic Floor Repair System family of devices. It consists of permanently-implanted mesh assemblies and non-implanted surgical instruments that are used as aids to place the mesh assembly in the pelvic floor.

Indications for Use
The Elevate Prolapse 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, vaginal wall prolapse repairs including anterior and posterior wall repairs, vaginal suspension, reconstruction of the pelvic floor and tissue repair.

Comparison to Predicate Devices
The Elevate System is identical to the previous version with the exception of a synthetic phosphorylcholine (PC) polymer coating being added to the center IntePro Lite section of the mesh assembly.

Supporting Information
A Design Failure Mode Effects and Criticality Analysis (dFMECA) was used to assess the impact of the modification. The performance parameters which were identified as potentially able to be affected by the modification were tested as mitigation. The testing demonstrated that the risks identified have been mitigated and that no new issues related to safety or efficacy were raised.

3. Labeling

- Draft Labeling and Instructions for Use for the Elevate System with *PC coated* IntePro Lite are provided in **Appendix A.**

- A copy of the predicate Labeling and Instructions for Use for the Elevate System with IntePro Lite are provided in **Appendix B.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

American Medical Systems
% Ms. Denise Thompson
Sr. Regulatory Affairs Specialist
10700 Bren Road West
MINNETONKA MN 55343

SEP 28 2012

Re: K090713
Trade/Device Name: Elevate Prolapse Repair System with PC Coated IntePro Lite
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTP
Dated: March 17, 2009
Received: March 18, 2009

Dear Ms. Thompson:

This letter corrects our substantially equivalent letter of April 2, 2009.

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,

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

1.5 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K090713

Device Name: Elevate Prolapse Repair System with PC Coated IntePro Lite

Indications For Use:

The AMS Elevate Prolapse 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, 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)

Daniel Krause for MXM 4/16/09

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

510(k) Number K090713

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

510(k) Number_____