AMS

JUL 20 2012

Section 5 — 510(k) Summary

Submitter's Name and Address

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Date the Summary was Prepared

July 20, 2012

Device Classification Name

Mesh, surgical, gynecologic, for pelvic organ prolapse, transvaginally placed (OTP)
Mesh, surgical, non-synthetic; urogynecologic, for pelvic organ prolapse, transvaginally placed (PAI)

Device Common/Usual Name

Surgical Mesh

Device Trade/Proprietary Name

Elevate® Anterior and Apical Prolapse Repair System
Elevate® Apical and Posterior Prolapse Repair System
Elevate® Apical and Posterior Prolapse Repair System with InteXen® LP

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Device Trade/Proprietary Name

Elevate® Anterior and Apical Prolapse Repair System
Elevate® Apical and Posterior Prolapse Repair System
Elevate® Apical and Posterior Prolapse Repair System with InteXen® LP

Product Code

OTP & PAI

Classification of Device

Class II / 21 CFR § 878.3300

Predicate Device(s)

Device Name	Submission Number
AMS Elevate Anterior and Apical Prolapse Repair System with IntePro Lite	K082677
AMS Elevate Apical and Posterior Prolapse Repair System with IntePro Lite AMS Elevate Apical and Posterior Prolapse Repair System with InteXen LP	K082730

Device Description

Each Elevate System consists of a permanently-implanted graft and non-implantable surgical instruments that can be used as aids to transvaginally place the graft assembly in the pelvic floor. The graft assemblies for the Elevate Anterior & Apical Prolapse Repair System and Elevate Apical & Posterior Prolapse Repair System are made from polymeric mesh (IntePro Lite), and in the case of the Elevate Apical & Posterior Prolapse Repair System with InteXen LP, the graft assembly is made from a combination of lyophilized porcine dermis and polymeric mesh (IntePro Lite).

The devices are identical to the predicate devices, AMS Elevate Prolapse Repair Systems, with the exception of the modification to the Apical Needle Passer Sheath. There are no changes to the implant graft design, shape, size, and material. The revisions to the indications for use of the modified devices are to further clarify the intended use of Elevate System as a kit for transvaginal surgical treatment.

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Existing Intended Use & Proposed Indication for Use

Existing indications for use

Elevate Anterior and Apical Prolapse Repair System
The Elevate Anterior & Apical Repair System is intended for the treatment of anterior and/or apical vaginal prolapse.

Elevate Apical and Posterior Prolapse Repair System
The Elevate Apical & Posterior Repair System is intended for the treatment of apical and/or posterior vaginal prolapse.

Elevate Apical and Posterior Prolapse Repair System with InteXen® LP
The Elevate Apical & Posterior Repair System is a surgical mesh kit intended for transvaginal surgical treatment to correct posterior vaginal wall prolapse and vaginal apical prolapse. The kit includes instrumentation for transvaginal placement.

Proposed indications for use

The following are revisions to the indications for use to further clarify that the Elevate System Repair Systems are intended for transvaginal surgical treatment.

Elevate Anterior and Apical Prolapse Repair System
The Elevate Anterior & Apical Repair System is a surgical mesh kit intended for transvaginal surgical treatment to correct anterior wall prolapse and vaginal apical prolapse.

Elevate Apical and Posterior Prolapse Repair System
The Elevate Apical & Posterior Repair System is a surgical mesh kit intended for transvaginal surgical treatment to correct posterior wall prolapse and vaginal apical prolapse.

Elevate Apical and Posterior Prolapse Repair System with InteXen® LP
The Elevate Apical & Posterior Repair System is a surgical mesh kit intended for transvaginal surgical treatment to correct posterior vaginal wall prolapse and vaginal apical prolapse.

Summary of the Technological Characteristics to the Predicate Device(s)

The modification to the Elevate Prolapse Repair Systems are deemed equivalent to the current device and there are no changes to the device intended use and/or device functional scientific technology.

The subject devices use the same surgical approach and implant placement procedures as the predicate devices.

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Summary of Non-Clinical & Clinical Testing

The modified sheath of the Elevate Anterior and Apical Prolapse Repair System, Elevate Apical & Posterior Prolapse Repair System, and Elevate Apical & Posterior Prolapse Repair System with InteXen LP has been tested for design verification and biocompatibility (cytotoxicity & physiochemical testing). Design verification testing of the sheath included the following tests:

- sheath compression strength and depth stop strength,
- trigger/sheath locking interface push strength,
- sheath cutout shear off strength and trigger/sheath locking interface pull strength
- sheath engagement force into lock

There were no modifications made to the packaging or sterilization of the devices as a result of the change; thus, no additional testing was required. There was no change to the intended use or the implant procedure as a result of the change; thus the Elevate Prolapse Repair Systems have equivalent clinical performance to the predicate devices and no clinical testing was required to support the sheath modification

American Medical Systems considers the Elevate Anterior & Elevate Posterior devices' product performance to be substantially equivalent to the predicate devices.

Substantial Equivalence

The modified Elevate Anterior and Elevate Posterior devices use the same surgical approach and implant placement procedures as the predicate devices, Elevate Anterior & Elevate Posterior.

The modified Elevate Anterior and Elevate Posterior devices have identical intended use, identical implant materials, identical sterilization methods; and similar delivery tool materials/characteristics as the predicate.

The proposed Elevate Anterior and Elevate Posterior device performance and fundamental scientific technology remains unchanged. The differences between the proposed device and the predicate device do not negatively affect the safety and effectiveness of the device.

Conclusion

AMS considers the modified Elevate Anterior and Elevate Posterior devices to be substantially equivalent to the predicate devices.

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Manufacturing Facility American Medical Systems, Inc. 10700 Bren Road West Minnetonka, MN 55343 Establishment Registration Number: 2183959
Sterilization Facility Sterigenics US, Inc. 7775 S Quincy St. Willowbrook, IL 60527 Establishment Registration Number: 1450293

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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JUL 20 2012

Re: K121612
Trade/Device Name: Elevate® Anterior and Apical Prolapse Repair System
Elevate® Apical and Posterior Prolapse Repair System
Elevate® Apical and Posterior Prolapse Repair System with InteXen® LP
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OTP, PAI
Dated: May 31, 2012
Received: June 28, 2012

Dear Ms. Latchman:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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" (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/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

Section 6 — Statement of Indications for Use

510(k) Number: K121612

Device Name: Elevate® Anterior and Apical Prolapse Repair System

Indications for Use:

Elevate Anterior and Apical Prolapse Repair System
The Elevate Anterior & Apical Repair System is a surgical mesh kit intended for transvaginal surgical treatment to correct anterior wall prolapse and vaginal apical prolapse.

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)

Benjamin R. Fisch 7/20/12

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121612

Section 6 — Statement of Indications for Use

510(k) Number: K121612

Device Name: Elevate® Apical and Posterior Prolapse Repair System

Indications for Use:

Elevate Apical and Posterior Prolapse Repair System
The Elevate Apical & Posterior Repair System is a surgical mesh kit intended for transvaginal surgical treatment to correct posterior wall prolapse and vaginal apical prolapse.

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)

20 July 2012

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121612

Section 6 — Statement of Indications for Use

510(k) Number: K121612

Device Name: Elevate® Apical and Posterior Prolapse Repair System with InteXen® LP

Indications for Use:

Elevate Apical and Posterior Prolapse Repair System with InteXen® LP
The Elevate Apical & Posterior Repair System is a surgical mesh kit intended for transvaginal surgical treatment to correct posterior vaginal wall prolapse and vaginal apical prolapse.

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)

20 July 2012

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121612