

K08 2387

DEC 04 2008

510(k) Summary Statement

Submitter: American Medical Systems (AMS)
10700 Bren Road West
Minnetonka, MN 55343

Contact Person: Sarah Peterson
Phone: 952.930.6431
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Device Common Name: Surgical Mesh

Device Trade Name: Apogee and Perigee Systems with IntePro Lite and
InteXen LP, 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: Apogee and Perigee Systems with IntePro Lite and
InteXen LP (K051485), Part of the AMS Pelvic
Floor Repair System

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 Apogee and Perigee Systems with IntePro Lite and InteXen LP are sterile, single use procedure kits that consist of stainless steel, curved needle passers and an implantable mesh assembly.

Summary of Testing

The components of the Apogee and Perigee Systems with IntePro Lite and InteXen LP 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

American Medical Systems (AMS)
%. Ms. Sarah Peterson
10700 Bren Road West
Minnetonka, Minnesota 55343

DEC 04 2008

Re: K082387

Trade Name: Apogee and Perigee Systems with IntePro Life and InteXen LP, Part of the
AMS Pelvic Floor Repair System

Regulation Number: 21 CFR 878.3300

Regulation Names: Surgical Mesh

Regulatory Class: II

Product Code: FTL

Dated: November 3, 2008

Received: November 4, 2008

Dear Ms. Peterson:

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.

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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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

K082387

Indications for Use Statement

510(k) Number:
(If known)

Device Name: Apogee and Perigee Systems with IntePro Lite and InteXen LP, Part of the AMS Pelvic Floor Repair System

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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Nick Dyer for man

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

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