510(k) Summary
As required by 21 CFR 807.92 (b)

510(k) Number: K100807

Date Revised: June 2, 2010

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Submitter Information:

Submitter's Name/ Address	American Medical Systems, Inc. 10700 Bren Road West Minnetonka, MN 55434-USA
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510(k) Summary

Device(s) Information:

Trade Name:	MiniArc Precise™ Single-Incision Sling
Common Name:	Surgical Mesh
Classification Name:	Surgical Mesh, Polymeric
Class:	Class II / 21 CFR § 878.3300
Product Code:	PAH

Predicate Device:

Device Name	Submission Number	Clearance Date
MiniArc® Sling System	K070065	March 1, 2007
MiniArc® Sling System	K071902	August 24, 2007
MiniArc® Sling System	K073703	January 20, 2008

Device Description:

The MiniArc Precise Single-Incision Sling System (MiniArc Precise) is a modification of the currently commercialized device, MiniArc Single-Incision Sling System (MiniArc), which consist of one sterile mesh sling and one sterile surgical instrument used for sub-urethral sling placement.

The minor modifications to MiniArc for the development of the MiniArc Precise are as follows:

- Self-fixating tips on the mesh sling are for a "secure connection" (snap-fit) to the delivery tool needle tip.
- Delivery tool has an actuating needle tip release mechanism for the mesh sling.
- Mesh slings center-length dimensions are modified and the mesh sling arms are knit with reinforcement fibers.

The MiniArc Precise is available in two configurations; each configuration contains one sterile mesh sling and one sterile delivery tool. The identical delivery tool is used with both configurations. The configurations are identified by the mesh sling option, either the short center-length mesh or the long center-length mesh. The mesh sling and mesh arms material for MiniArc Precise is the same knitted polypropylene monofilament material used in the predicate, MiniArc.

MiniArc Precise uses the same surgical approach and the same mesh placement procedures as the predicate device, MiniArc. The MiniArc Precise device is for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD). MiniArc Precise device is for single use only and is not to be re-sterilized.

Indications for Use:

Existing Indications for Use:

The MiniArc® Sling System (MiniArc) is intended for the placement of a suburethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Proposed Indications for Use:

There are no changes to the existing indications for use with the exception of the device name, as shown below:

The MiniArc Precise™ Single-Incision Sling System is intended for the placement of a suburethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency(ISD).

Comparison to Predicate Device:

The proposed MiniArc Precise and the predicate device, MiniArc, consist of one sterile mesh sling and one sterile surgical instrument (needle passer or deliver tool).

The MiniArc Precise and MiniArc devices are intended for the placement of a sub-urethral mesh sling under the female urethra, with self-fixating tips in the right and left obturator. The mesh sling is placed with the use of a surgical instrument. The surgical instrument is a stainless steel curved needle with an attached plastic handle. The tip portion of surgical instrument is configured to allow for secure connection and placement of the mesh sling. The mesh sling is a piece of knitted polypropylene mesh with self-fixating tips at each end. The mesh sling is intended to remain in the body as a permanent implant and is not absorbed or degraded by the action of tissue in-growth or tissue enzymes.

These device systems are for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD). These devices are for single use and are not to be re-sterilized.

The MiniArc Precise has the same intended use, same implant materials, and same sterilization methods. The MiniArc Precise also uses similar manufacturing processes and similar delivery tool materials/characteristics to the predicate device, MiniArc.

Summary of Non-Clinical Testing / Statement of Substantial Equivalence

The non-clinical testing included the assessment of the MiniArc Precise physical properties; ability to achieve its intended use; and substantial equivalence to the MiniArc predicate device.

- Bench testing confirmed the product performance of the MiniArc Precise to be suitable for its intended use: the same intended use as the predicate device.
- Animal testing confirmed the tissue fixation and tissue response is equivalent to the predicate device.
- Cadaver lab testing confirmed the surgical procedure, using the "secure connection" self-fixating tips to the delivery tool needle, is the equivalent to the predicate device.
- Biocompatibility assessment ensured the MiniArc Precise materials are biocompatible based on the similarity of the materials to the predicate device.

The following table is a summary of non-clinical testing conducted in accordance to industry standards/regulations:

Test	Industry Standards
Design Verification	Quality System Requirements FDA 21 CFR Part 820.20 EN ISO 13485: 2003; Design Controls FDA 21 CFR Part 820.30
Device Performance	Quality System Requirements FDA 21 CFR Part 820.20 EN ISO 13485: 2003; Design Controls FDA 21 CFR Part 820.30
Animal Model	FDA 21 CRR: Part 58 Good Laboratory Practice Regulations
Packaging	ISO 11607: 2006 Part 1 and Part 2: Packaging for Terminal Sterilized Medical Devices
Shelf Life	ISO 11607: 2006 Part 1, 6.4 Stability Testing
Biocompatibility	ISO 10993-1: 2009 Biological Evaluation of Medical Devices.
Sterilization	ISO 11135: Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization and EN ISO 13485.

The proposed MiniArc Precise device performance, intended use and fundamental scientific technology remain unchanged from the predicate device. The proposed modifications do not change the mesh fixation mechanism found in the predicate device, MiniArc. The tissue fixation element fixates the mesh until tissue in-growth occurs through the pores of the mesh. The mesh sling will still be used as a supporting framework in areas where the connective tissue has weakened or ruptured. The mesh sling, with self-fixating tips, is intended to remain in the body as a permanent implant.

American Medical Systems considers the MiniArc Precise product performance to be significantly equivalent to the predicate device, MiniArc, because there are no changes to the product performance specifications; device intended use; or device functional scientific technology.

Conclusion

The above non-clinical testing for the MiniArc Precise demonstrates product performance to be substantially equivalent and demonstrates that it is as safe and effective as the predicate device, MiniArc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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SEP 28 2012

Re: K100807
Trade/Device Name: MiniArc Precise™ Single-Incision Sling System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAH
Dated: April 23, 2010
Received: April 26, 2010

Dear Ms. Semlak:

This letter corrects our substantially equivalent letter of June 7, 2010.

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Name of Devices: MiniArc Precise™ Single-Incision Sling System

Indications for Use: The MiniArc Precise™ Single-Incision Sling System is intended for the placement of a sub-urethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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