

American Medical Systems
K131229/ Amendment 1;
Special 510(k) Submission **Changes Being Effectuated**
Sparc™ Sling System and Monarc™, Monarc™ + and Monarc™ C Subfascial Hammock

510(k) Summary

Date Prepared: November 1, 2013

Submitter's Name/ Address: American Medical Systems, Inc.
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DEC 05 2013

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American Medical Systems
K131229/ Amendment 1;
Special 510(k) Submission **Changes Being Effected**
Sparc™ Sling System and Monarc™, Monarc™ + and Monarc™ C Subfascial Hammock

Proposed Device:

Device Proprietary Name: Sparc™ Sling System and Monarc™, Monarc™ + and Monarc™ C Subfascial Hammock
Common Name: Surgical Mesh
Classification Name: Surgical Mesh, polymeric
Class: Class II / 21 CFR 878.3300
Product Code: OTN

Predicate Devices:

Sparc Sling System (Sparc) and Monarc, Monarc + and Monarc C Subfascial Hammock (Monarc) device; K081613

Proposed Device Description:

The Sparc and Monarc related device descriptions are as followed:

The Sparc device is a sterile, single use procedure kit consisting of:

- Two stainless steel, curved, 21-cm long, needle passers. One end of each needle passer is keyed to allow for secure placement of the connectors. Each needle passer has a plastic handle attached.
- One piece of AMS Polypropylene sling mesh with attached connectors. The AMS Polypropylene sling mesh is constructed of polypropylene monofilament that is precut to 1.1 cm width x 50 cm length. An absorbable tensioning suture is threaded into the length of the sling mesh to allow for tensioning adjustment of the sling mesh after placement in the patient is achieved. Two plastic sheaths that overlap in the center of the sling mesh cover the sling mesh and protect it during placement. The connectors are attached to the vaginal ends of the Sparc needle passers during the procedure. The AMS Polypropylene sling mesh is intended to remain in the body as a permanent implant and the mesh component is not absorbed or degraded by the action of tissue ingrowth or tissue enzymes.

The Monarc devices are sterile, single use procedure kits, each consisting of:

- Two stainless steel, curved needle passers. The tip portion of each needle passer is configured to allow for secure placement of the connectors. Each needle passer has a plastic handle attached.
- An assembly including one piece of loosely knitted polypropylene mesh, two removable plastic insertion sheaths attached to the mesh, and two connectors attached to the insertion sheaths. The mesh is constructed of polypropylene

monofilament. An absorbable tensioning suture is threaded into the length of the mesh to allow for tensioning adjustment of the mesh after placement in the patient is achieved. The plastic covering also affords convenient travel of the mesh through the tissue. The connectors are attached to the tip portions of the Monarc needle passers during the procedure. The loosely knitted polypropylene mesh is intended to remain in the body as a permanent implant. The mesh component is not absorbed or degraded by the action of tissue in-growth or tissue enzymes.

Proposed Device Intended Use (Indication for Use):

Sparc Sling System (Sparc):

Intended for the placement of pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and /or intrinsic sphincter deficiency.

Monarc, Monarc + and Monarc C Subfascial Hammock (Monarc) device:

Intended for the placement of suburethral mesh for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and /or intrinsic sphincter deficiency.

Summary of the Technical Characteristics Compared to the Predicate Device(s):

All characteristics of the proposed device are identical to those of the predicate, including design, material construction, manufacturing process, and intended use. There is no change to the technical characteristics for this 510(k).



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

December 5, 2013

American Medical Systems, Inc.
David H. Mueller
Principal Regulatory Affairs Specialist
10700 Bren Road West
Minnetonka, MN 55343

Re: K131229
Trade/Device Name: Sparc™ Sling System and Monarc™, Monarc™ + and
Monarc™ C Subfascial Hammock Systems
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: November 1, 2013
Received: November 6, 2013

Dear David H. Mueller,

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 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,

Herbert P. Lerner -S

for

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 4**Indication for Use Statement**

510(k) Number: K131229

Device Name:

Sparc™ Sling System and
Monarc™, Monarc™ + and Monarc™ C Subfascial HammockSystems

Indications for Use:

Sparc System:

Intended for the placement of pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Monarc, Monarc + and Monarc C Systems:

Intended for the placement of suburethral mesh for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use (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)

Herbert P. Lerner -S

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