K041948

AUG 11 2004

American Medical Systems

510(k) Summary

Submitter:	American Medical Systems 10700 Bren Road West Minnetonka, Minnesota 55343
Date Prepared:	July 19, 2004
Contact:	Kristyn M. Benson Sr. Regulatory Affairs Specialist
Proprietary Name:	SPARC™, MONARC™, BioArc SP™, and BioArc TO™ Sling Systems
Common Name:	Surgical Mesh
Device Product Code & Classification:	Class II; OTN
Predicate Device:	SPARC™ Sling System (K021263) MONARC™ Sling System (K023516) BioArc SP™ Sling System (K030123) BioArc TO™ Sling System (K040538)

Device Description:
The SPARC™, MONARC™, BioArc SP™, and BioArc TO™ Sling Systems are sterile, single use procedure kits that consist of two stainless steel, curved needle passers (also known as insertion tools); AMS polypropylene sling mesh and suture; and two plastic sheaths that cover and protect the sling mesh during placement.

Intended Use:
The SPARC™, MONARC™, BioArc SP™, and BioArc TO™ Sling Systems are intended for the placement ofa pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Statement of Technological Comparison:
The risk analysis and the verification/validation activities reported in this Special 510(k) application substantiate equivalence to the predicate devices and did not raise any new questions of safety or efficacy.

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

Ms. Kristyn M. Benson
Sr. Regulatory Affairs Specialist
American Medical Systems
10700 Bren Road West
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SEP 28 2012

Re: K041948
Trade/Device Name: SPARC™, MONARC™, BioArc Sp™, and BioArc T1O™ Sling Systems
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: July 19, 2004
Received: July 20, 2004

Dear Ms. Benson:

This letter corrects our substantially equivalent letter of August 11, 2004.

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: (Pending) K041948

Device Name: SPARC™, MONARC™, BioArc SP™, and BioArc TO™ Sling Systems

Indications for Use:

The SPARC™, MONARC™, BioArc SP™, and BioArc TO™ Sling Systems are intended for the placement ofa pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use X **AND/OR** **Over-the-Counter-Use** _____
(Per 21 CFR 801 Subpart D) **(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)

Miriam C. Provost

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

510(k) Number K041948