510(k) Summary of Safety and Effectiveness
American Medical Systems, Inc.'s *Soft Tissue Approximation System*

SEP - 5 2001

510(k) Number K012342

July 23, 2001

Submitter/Contact Name:
Avraham Biran / Elsa Linke
American Medical Systems, Inc.
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Trade Name:

AMS Soft Tissue Approximation System

Classification Name:

Implantable Clip and Applicator

Predicate Devices:

Acufex Microsurgical's T-Fix and T-Bar (K942442 and K925573, respectively) and AMS Inc's Fascial-Anchoring System (K010277).

Indication for Use:

The AMS soft tissue approximation system ("ASTA") is intended for use as a general use suture retention device. The ASTA system provides a method to deploy and anchor suture internally from a single access point, which may be used to grasp, manipulate, or affix the attached tissue.

Device Description:

The AMS soft tissue approximation system has two components: a clip and an applicator. The clip is shaped as a rod and is available in two different sizes. Each clip has a central hole through which non-absorbable suture up to and including size No. 1 may be threaded. The applicator is composed of a straight or curved stainless steel tube in which the tip of the clip is positioned and has a handle with a release button for clip deployment. The choice of shaft configuration and clip size depends upon the desired application.

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Technological Characteristics and Performance:

All materials used in the AMS soft tissue approximation system are either commonly used in medical applications or have been proven to be biocompatible through biocompatibility testing. Bench testing has demonstrated that the device is safe and effective and that its performance is substantially equivalent to a 510(k)-cleared device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2001

Ms. Elsa A. Linke
Regulatory Affairs
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K012342
Trade/Device Name: AMS Soft Tissue Approximation System
Regulation Number: 878.4300, 878.4930
Regulatory Class: II
Product Code: FZP, KGS
Dated: July 23, 2001
Received: July 24, 2001

Dear Ms. Linke:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Walker, MD for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012342

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: AMS Soft Tissue Approximation system, consisting of Applicators and Clips.

Indications for Use: The AMS Soft Tissue Approximation system is intended for use as a general use suture retention device. The ASTA system provides a method to deploy and anchor suture internally from a single access point, which may be used to grasp, manipulate, or affix the attached tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of General, Restorative and Neurological Devices
510(k) Number _____

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

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

510(k) Number K012342