

American Medical Systems, Inc.
Pfizer Hospital Products Group
10700 Bren Road West
Minnetonka, MN 55343
Tel 612 933 4666 Fax 612 930 6592
Toll Free 800 328 3881

JUL - 9 1997



SUMMARY OF SAFETY AND EFFECTIVENESS

I. SUBMITTER

Name and Address: American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, MN 55343 USA

Contact Person: John M. Otto

Date of Summary Preparation: April 9, 1997

Date Summary Amended: June 9, 1997

Establishment Registration Number: 2183959

II. DEVICE NAME

Device Common or Usual Name: Staple, Fixation, Bone Appliance for Reconstruction of Bone to Soft Tissue

Device Trade Name: AMS Mainstay™ Urologic Bone Anchor

III. PREDICATE DEVICE

Howmedica® Mainstay™ Soft Tissue Anchor K953531

IV. DEVICE DESCRIPTION

The AMS Mainstay™ Urologic Bone Anchor for bladder neck suspension procedures are titanium alloy implants. They are used to anchor suture material within cortical or cancellous bone sites, thereby providing a means for firmly securing soft tissue to bone. Two (2) Mainstay™ anchors are packaged in one box.

The recommended nonabsorbable suture size for the 3.5 mm Mainstay™ anchor is up to a maximum size of #0 (USP) when using two (2) strands and up to a maximum size of #2 when using a single strand.

V. INDICATIONS FOR USE

The AMS Mainstay Urologic Bone Anchor is intended only for the fixation of surgical suture material to the pelvis for the purpose of bladder neck suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency.

VI. COMPARISON TO PREDICATE DEVICE

The AMS Mainstay™ Urologic Bone Anchor with the proposed modifications is substantially equivalent to the currently marketed Howmedica® Mainstay™ Soft Tissue Anchor.

a. Intended Use

The AMS Mainstay™ Urologic Bone Anchor with the proposed modifications has the same intended use as one of the indications cleared for the currently marketed Howmedica® Mainstay™ Soft Tissue Anchor (Bladder Neck Suspension).

b. Device Performance

The AMS Mainstay™ Urologic Bone Anchor with the proposed modifications is comparable with respect to intended use and technological characteristics to the Howmedica® Mainstay™ Soft Tissue Anchor which is in commercial distribution in the United States. American Medical Systems has provided a table on the following page which compares the similarities and differences of the devices.

c. Bench Testing

The only new test performed for the AMS Mainstay™ Urologic Bone Anchor was for the Maximum Suture to Bone Anchor Interface Break Force for Monofilament Suture.

The objective of the test was to measure the maximum force required to break monofilament suture that has been attached to a bone anchor, and to compare these data to the minimum knot-pull strength requirements in the USP for the same size and class of suture. Two (2) sizes of a nonabsorbable monofilament suture were evaluated in this test.

All of the sutures tested exceeded the USP recommended minimum knot-pull strength for their respective class and size of suture (non-absorbable, Class I). The average suture break force for both the #3-0 and the #2 exceeded the USP minimum recommended knot-pull strength by more than a factor of four (4).

In summary, American Medical Systems has provided information within the 510(k) Premarket Notification to indicate that the AMS Mainstay™ Urologic Bone Anchor with the proposed modifications is safe and effective for its intended use (Bladder Neck Suspension) as one of the indications cleared for the currently marketed Howmedica® Mainstay™ Soft Tissue Anchor. Additionally, the modified AMS Mainstay™ Urologic Bone Anchor has been shown to be comparable in terms of intended use and technological characteristics to the Howmedica® Mainstay™ Soft Tissue Anchor currently in

commercial distribution. The data and information provided within this 510(k) Premarket Notification adequately support that the AMS Mainstay™ Urologic Bone Anchor with the proposed modifications is substantially equivalent to the Howmedica® Mainstay™ Soft Tissue Anchor that is currently in commercial distribution.

EQUIVALENCY TABLE

American Medical Systems Mainstay Urologic Bone Anchor	Howmedica Mainstay Soft Tissue Anchor (K953531)	Zimmer Statak Anchors (K926384)
INTENDED USE		
a. Soft Tissue Attachment to Bone	X	X
b. Bladder Neck Suspension	X	X
MATERIAL		
Ti-6Al-4V	X	X
DESIGN		
a. Cancellous Screw Thread	X	X
b. Self-drilling, Self-tapping	X	X
c. Proximal Hole for Suture Attachment	X	X
OPERATIONAL PRINCIPLES		
a. Attachment Site for Suture	X	X
b. Anchored by Screw Threads	X	X
c. Removable	X	X



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John M. Otto
Senior Regulatory Affairs Associate
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K971332
AMS Mainstay™ Urologic Bone Anchor
Regulatory Class: II
Product Codes: MBI and HWC
Dated: June 9, 1997
Received: June 10, 1997

JUL - 9 1997

Dear Mr. Otto:

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 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.

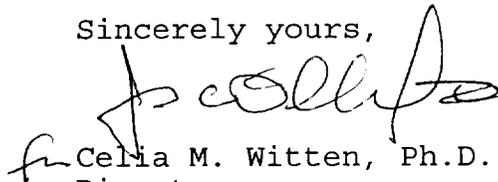
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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 pre-market 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.

Page 2 - Mr. John M. Otto

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosure

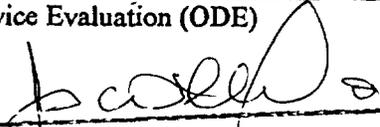
510(k) Number (if Known): K971332

Device Name: AMS Mainstay™ Urologic Bone Anchor

Indications For Use: The AMS Mainstay™ Urologic Bone Anchor is intended only for the fixation of surgical suture material to the pelvis for the purpose of bladder neck suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency

(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 Devices
510(k) Number K971332

Prescription Use X

OR

Over-The Counter Use

(Per 21 CFR 801.109)