

OCT 22 2001

K012503
10F2



CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor: Arthrotek, Inc.
(A wholly owned subsidiary of Biomet, Inc.)
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587
Establishment Registration No.: 1825034

Contact Person: Sara B. Shultz
Biomet Manufacturing, Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (219) 267-6639
FAX: (219) 372-1683

Proprietary Name: Metal Screw Anchor

Common or Usual Name: screw anchor

Classification Name: Fastener, Fixation, Non-degradable, Soft Tissue

Device Product Code: 87MBI and 87HWC

Legally Marketed Devices To Which Substantial Equivalence is Claimed:
Harpoon Suture Anchor (Biomet, Inc., K943806/K973775)

Indications for Use: Indications for the Metal Screw Anchor include use in soft tissue reattachment procedures in the shoulder, wrist, elbow, and knee.
Specific indications are as follows:

Shoulder Indications – Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair.

Wrist/Hand Indications – Scapholunate ligament reconstruction, ulnar/radial collateral ligament reconstruction.

Ankle/Foot Indications – Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, mid- and forefoot reconstruction.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

K012503
20F2

BIOMET

CORPORATE HEADQUARTERS

Elbow Indications – Ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction.

Knee Indications – Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis, and patellar ligament/tendon repair.

Device Description: The Metal Screw Anchor is a screw-type anchor used to provide means for attaching soft tissue to bone during healing. The device is manufactured out of titanium (Ti-6Al-4V) and is available in two sizes, 3.0 mm and 5.0 mm. The screw anchor consists of a screw portion and a head portion.

The 3.0 mm size anchor will be available with a monofilament suture, #1 suture, or #2 suture while the 5.0 mm size anchor will be available with a monofilament suture, two #2 sutures or a #5 suture. The Metal Screw Anchor will be packaged sterile and will be preloaded on a driver with suture.

Summary of Technologies: The Metal Screw Anchor's technological characteristics (materials, design, sizes, and indications) are similar to the predicate device.

Non-Clinical Testing: Mechanical testing was performed to establish substantial equivalence to the predicate devices.

Clinical Testing: Clinical testing was not used to establish substantial equivalence to predicate devices.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com



OCT 22 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sara B. Shultz
Regulatory Specialist
Biomet, Inc.
P. O. Box 587
Warsaw, Indiana 46581-0587

Re: K012503
Trade Name: Metal Screw Anchor
Regulation Number: 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances
and accessories
Regulatory Class: Class II
Product Code: MBI
Dated: August 2, 2001
Received: August 3, 2001

Dear Ms. Shultz:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

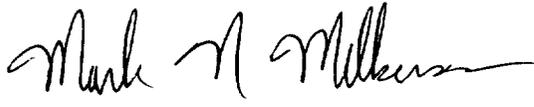
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

Page 2 - Ms. Sara Shultz

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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 Part 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,

for 

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

Enclosure

510(k) NUMBER (IF KNOWN): K012503

DEVICE NAME: Metal Screw Anchor

INDICATIONS FOR USE: Indications for the Metal Screw Anchor include use in soft tissue reattachment procedures in the shoulder, wrist, elbow, and knee.

Specific indications are as follows:

Shoulder Indications – Bankart repair, SLAP lesion repair, acromioclavicular separation, rotator cuff repair, capsule repair, or capsulolabral reconstruction, biceps tenodesis, and deltoid repair.

Wrist/Hand Indications – Scapholunate ligament reconstruction, and ulnar/radial collateral ligament reconstruction.

Ankle/Foot Indications – Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, mid- and forefoot reconstruction.

Elbow Indications – Ulnar or radial collateral ligament reconstruction, and biceps tendon reconstruction.

Knee Indications – Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis, and patellar ligament/tendon repair.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)

for Mark A. Millers

(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K012503