OCT 2 9 2004

K042460

510(k) Summary

Applicant/Sponsor:
Arthrotek Inc.
(A wholly owned subsidiary of Biomet, Inc.)
56 Bell Drive
Warsaw, IN 46582
FDA Registration #: 1825034

Contact Person:
Gary Baker
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587
Telephone: (574) 372-1568
Fax: (574) 372-1683

Proprietary Name: Ti - Screw Anchor SP

Common Name: Screw Anchor

Classification Name: Fastener, Fixation, Non-degradable, Soft Tissue
21 CFR §888.3040

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Metal Screw Anchor (K012503) – Biomet Inc.
Harpoon and Mini Harpoon Suture Anchors (K973775) – Biomet Inc.

Device Description: The Ti – Screw Anchor SP consists of a screw tip, a screw body, and an internal cross pin to attach the suture. The screw tip engages the bone while the screw body provides the means to drive the anchor in, and the pin is used to attach the suture to the anchor.

Intended Use: Indications For Use: The Ti-Screw Anchor SP is indicated for use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, 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 – 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, 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.

Summary of Technologies: The Ti – Screw Anchor SP has the same intended use, functional characteristics, and uses the same titanium alloy as the predicate Metal Screw Anchor device.

Non-Clinical Testing: Mechanical testing found the Ti – Screw Anchor SP to be substantially equivalent to the predicate Harpoon Suture Anchor and Metal Screw Anchor.

Clinical Testing: No clinical testing was provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2004

Mr. Gary Baker
Regulatory Specialist
Biomet Manufacturing Corporation
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K042460
Device Name: Ti - Screw Anchor SP
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: MBI, GAS, GAT
Dated: September 9, 2004
Received: September 10, 2004

Dear Mr. Baker:

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.

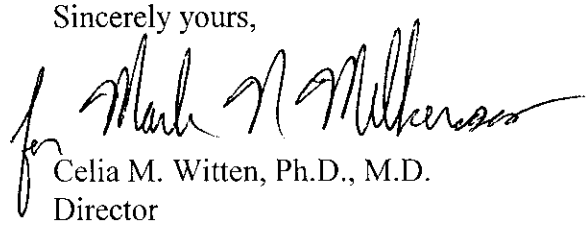
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

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), please contact the Office of Compliance at (240) 276- 0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



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

Indications for Use

510(k) Number (if known): K042460

Device Name: Ti – Screw Anchor SP

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Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Part 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)

for Mark N Milhous

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

510(k) Number K042460