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BIOMET

510(k) Summary

Applicant/Sponsor: Arthrotek, Inc.

Contact Person: Tracy J. Bickel
Regulatory Associate

Proprietary Name: Titanium Toggle Button(s)

Common Name: Soft Tissue Anchor

Classification Name: Fastener, fixation, nondegradable, soft tissue (888.3040)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- Cruciate Ligament Button (K813581): Biomet, Inc.
- Pre-Threaded EndoButton (K984550): Smith and Nephew, Inc.
- Endobutton Continuous Loop (K980155): Smith and Nephew, Inc.

Device Description: The Titanium Toggle Buttons are a toggle bar designed with one or two eyelets through which multiple loops of suture are threaded. There are two types of Toggle Buttons, the standard toggle button with two eyelets and the NS toggle button with one larger eyelet only. The suture loops provide a means to attach the soft tissue grafts to the toggle buttons. The loops are attached to the toggle button by putting the loops through the eyelet(s). This device is used to anchor the suture loops to bone.

Indications for Use: Fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) Reconstruction.

Summary of Technologies: The titanium Toggle Buttons are similar to or identical to predicate devices in terms of material, intended use, and size.

Non-Clinical Testing: Mechanical testing was utilized to determine that the Titanium Toggle Button(s) has a greater pull-out strength than that of the predicate devices.

Clinical Testing: None provided as a basis for substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2004

Ms. Tracy J. Bickel
Regulatory Associate
Biomet Manufacturing Corporation
56 E. Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K033838
Trade/Device Name: Titanium Toggle Button(s)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: December 8, 2003
Received: December 10, 2003

Dear Ms. Bickel:

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 (301) 594-4659. 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

510(k) Number (if known): K033858
Device Name: **Titanium Toggle Button(s)**
Indications for Use:

Fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) Reconstruction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

510(k) Number K033838