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BIOMET

510(k) Summary

SEP 17 2007

Preparation Date: June 20, 2007

Applicant/Sponsor: Biomet Sports Medicine (Formerly known as Arthrotek, Inc.)

Contact Person: Elizabeth Wray

Proprietary Name: Sleeve and Button Soft Tissue Devices

Common Name: Soft tissue fixation device

Classification Name:
- MAI (888.3030): Fastener, fixation, biodegradable, soft tissue
- MBI (888.3040): Fastener, fixation, nondegradable, soft tissue

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Device	Multitak SS Suture System™	BioRaptor™	Cruciate Ligament Button (PolySuture Button)
Manufacturer	Bonutti Research	Smith & Nephew	Biomet Sports Medicine*
510(k) Number	K973015	K053344	K813581

Device Description: The Sleeve and Button Soft Tissue Devices are comprised of a ZipLoop™, a Button or a coreless Sleeve structure, and a passing suture. A ZipLoop™ is constructed from ultra high molecular weight polyethylene (UHMWPE) or polyester. It is passed through the Sleeve or Button, thus creating a soft tissue fixation device that bunches or locks against the bone when deployed.

Indications for Use/Intended Use:
The Sleeve and Button Soft Tissue Devices utilizing ZipLoop™ Technology are intended for soft tissue to bone fixation for the following indications:

Shoulder
Bankart lesion repair, SLAP lesion repair, Acromio-clavicular repair, Capsular shift/capsulolabral reconstruction, Deltoid repair, Rotator cuff tear repair, Biceps tenodesis

Foot and Ankle
Medial/lateral repair and reconstruction, Mid- and forefoot repair, Hallux valgus reconstruction, Metatarsal ligament/tendon repair or reconstruction, Achilles tendon repair

Elbow
Ulnar or radial collateral ligament reconstruction, Lateral epicondylitis repair, Biceps tendon reattachment

Knee
Extra-capsular repair: MCL, LCL, and posterior oblique ligament
Iliotibial band tenodesis, Patellar tendon repair, VMO advancement, Joint capsule closure

Hand and Wrist
Collateral ligament repair, Scapholunate ligament reconstruction, Tendon transfers in phalanx, Volar plate reconstruction

Hip
Acetabular labral repair

In addition to the aforementioned indications, the Button Soft Tissue Devices (all sizes) and size specific Sleeve Soft Tissue Devices (as shown in Table 1) are indicated for the following:

Knee
ACL/PCL repair/reconstruction
ACL/PCL patellar bone-tendon-bone grafts
Double-Tunnel ACL reconstruction

Table 1

Sleeve Soft Tissue Devices: Specific Combinations for ACL/PCL Indications			
Loop Size		**Sleeve Size**	
UHMWPE/ Polypropylene	Polyester	UHMWPE/ Polypropylene	Polyester
#2-0 or >	--	#2 or >	--
#2-0 or >	--	--	#0 or >
--	#2 or >	--	#5 or >

Example: The following sleeve device combination may be used for ACL/PCL indications: #2-0 UHMWPE/Polypropylene Loop + #2 UHMWPE/Polypropylene Sleeve

Note: The loop and sleeve sizes denote the diameter of the original UHMWPE/Polypropylene or polyester braided fiber.

Summary of Technologies: The technological characteristics (materials, design, sizing, and indications) of the Sleeve and Button Soft Tissue Devices are similar or identical to the predicate device or other previously cleared devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

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

All trademarks are property of Biomet, Inc. except Multitak SS Suture System™ of Bonutti Research and BioRaptor™ of Smith & Nephew.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Manufacturing Corp.
% Ms. Elizabeth Wray
Regulatory Affairs Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

SEP 17 2007

Re: K071704
Trade/Device Name: Biomet Sleeve and Button Soft Tissue Devices
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, JDR
Dated: June 20, 2007
Received: June 21, 2007

Dear Ms. Wray:

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" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): K071704

Device Name: Sleeve and Button Soft Tissue Devices

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Hip
Acetabular labral repair

Prescription Use YES AND/OR Over-The-Counter Use NO
(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)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)