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BIOMET®

DEC 16 2008

## 510(k) Summary

**Preparation Date:** December 4, 2008

**Applicant/Sponsor:** Biomet Sports Medicine

**Contact Person:** Robert Friddle

**Proprietary Name:** ToggleLoc™ System

**Common Name:** Soft tissue anchor

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

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**
TightRope™ Syndesmosis Device - K043248 (Arthrex)
Sleeve and Button Soft Tissue Devices - K071704 (Biomet Sports Medicine)
Titanium Toggle Buttons – K033838 (Biomet Sports Medicine, formerly known as Arthrotek, Inc.)

**Device Description:** The ToggleLoc™ System contains toggle buttons and a Tophat suture button preloaded with sutures and/or fiber constructs. The suture button has multiple eyelets for attachment of fiber constructs and/or sutures. The fiber constructs and/or sutures are preloaded for the convenience of the surgeon for soft tissue attachment.

**Intended Use:** The ToggleLoc™ System Devices are intended for soft tissue to bone fixation for the following indications:

**Shoulder:** Bankart lesion repair, SLAP lesion repairs 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, Ankle Syndesmosis fixation (Syndesmosis disruptions) and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures (**only for ToggleLoc™ with Tophat**)

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

**Knee:** ACL/PCL repair / reconstruction, ACL/PCL patellar bone-tendon-bone grafts, Double-Tunnel ACL reconstruction, Extracapsular repair: MCL, LCL, and posterior oblique ligament, Illiotibial 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

**Mailing Address:**
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.372.1718
www.biomet.com

**Shipping Address:**
56 East Bell Drive
Warsaw, IN 46582

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**Summary of Technologies:** The technological characteristics (materials, design, sizing and indications) of the ToggleLoc™ System 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.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2008

Biomet Sports Medicine
% Mr. Robert Friddle
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587

Re: K083070
Trade/Device Name: ToggleLoc™ System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI, JDR
Dated: October 13, 2008
Received: October 15, 2008

Dear Mr. Friddle:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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): K083070

Device Name: ToggleLoc™ System

Indications for Use:

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**Hip:** Acetabular labral repair

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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



**510(k) Number** K083070