



MANUFACTURING CORP.

510(k) Summary

JUL 17 2008

**Preparation Date:** April 22, 2008

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

**Contact Person:** Becky Earl

**Proprietary Name:** Composite Hitch™ Suture Anchor

**Common Name:** Suture anchor

**Classification Name:** Fastener, fixation, biodegradable, soft tissue (21 CFR 888.3030)

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**

- Hitch™ LactoSorb® Suture Anchor, K061657, Biomet, Inc.
- Soft Tissue Screw and Washer, K012572, Biomet, Inc.
- Biocryl Rapide Bioknotless BR Anchor, K070925, DePuy Mitek

**Device Description:**

The Composite Hitch™ Suture Anchor is made with a composite, resorbable material. The soft tissue anchor, preloaded with polyethylene surgical suture, enables the user to insert the implantable anchor by screwing it in through a tapped pre-drilled hole or by simply pushing the point directly into the bone without pre-drilling a starter hole.

**Intended Use:**

Indications for the Composite Hitch™ Suture Anchor include use in soft tissue reattachment procedures in the shoulder, wrist/hand, elbow, and knee. Specific indications are as follows:

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

Wrist/Hand: Scapholunate ligament reconstruction

Elbow: Tennis elbow repair, Biceps tendon reconstruction, medial and lateral repairs, ulnar or radial collateral ligament reconstruction.

Knee: Extracapsular repair: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis, patellar ligament/tendon repair, vastus medialis obliquus (VMO) muscle advancement.

**Summary of Technologies:** The Composite Hitch™ Suture Anchor has similar or identical technological characteristics (design, materials, and functional performance) as the predicate devices.

**Non-Clinical Testing:** Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicate that the anchors are substantially equivalent to predicate anchors with similar indications for use.

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

*All trademarks are property of Biomet Inc.*

Mailing Address:  
 P.O. Box 657  
 Warsaw, IN 46781-0657  
 B-4 Freq. 800 348-6601  
 Office 574 267 1339  
 Main Fax 574 267 6167  
 www.biomet.com

Shipping Address:  
 200 East 10th Street  
 Warsaw, IN 46783



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUL 17 2008**

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

Re: K081172  
Trade/Device Name: Composite Hitch™ Suture Anchor  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation  
~~appliances and accessories~~  
Regulatory Class: Class II  
Product Code: JDR, HWC  
Dated: April 22, 2008  
Received: April 24, 2008

Dear Ms. Earl:

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.

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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): K081172

Device Name: Composite Hitch™ Suture Anchor

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Prescription Use  X   
(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)

Concurrence of CDRH, Office of Device Evaluation (ODE)



**(Division Sign-Off)**

**Division of General, Restorative,  
and Neurological Devices**

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