

DEC 16 2005

**Bonutti Research, Inc.
Multitak 6.0 mm Absorbable Anchor System
510(k) Premarket Notification**

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The following information is submitted in accordance with the requirements of 21 CFR 807.92:

Contact Person: Patrick Balsmann, MBA, MS, RAC
Director, Regulatory/Clinical Affairs & QA
Bonutti Research, Inc.,
P.O. Box 1367, Effingham, Illinois 62401
Phone: (217) 342-3412, ext. 321
Fax: (217) 342-1043

Date Prepared: September 29, 2005

Proprietary Name: Multitak 6.0 mm Absorbable Anchor System

Common Name: Absorbable Soft Tissue Anchor

Classification Name: Fastener, Fixation, Biodegradable, Soft Tissue.

Device Description: The Multitak 6.0 mm Absorbable Anchor System consists of a single use absorbable suture anchor implant and is intended for use as a load bearing or non-load bearing suture anchor in the attachment of soft tissue to bone in various arthroscopic and open surgical procedures. The 6.0 mm absorbable suture anchor implant is provided sterile and once passed with suture is inserted into a predrilled bone soft tissue repair site (i.e., rotator cuff repairs) with the use of disposable and reusable introduction devices. The threaded design of the suture anchor implant allows it to be screwed into the bone tissue repair site engaging cancellous bone and acts as an anchor in securing soft tissue to bone.

Indications for Use: The Multitak Splinter 6.0 mm Absorbable Anchor System is indicated for use in securing soft tissue to bone in such applications as the following:

Shoulder:

Bankart lesion repairs
Acromio-clavicular repairs
Deltoid repairs
Rotator cuff tear repairs
Biceps tenodesis
SLAP lesion repairs

Elbow, Wrist, & Hand:

Scapholunate ligament reconstruction
Ulnar collateral ligament reconstruction radial
Collateral ligament reconstruction
Biceps tendon reattachment

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510(k) Summary of Safety and Effectiveness
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Knee:

Extra-capsular repairs
 Medial collateral ligament repair
 Lateral collateral ligament repair
 Posterior oblique ligament repair
 Iliotibial band tenodesis
 Patellar tendon repair
 VMO advancement
 Joint capsule closure

Foot & Ankle:

Medial instability repair/reconstruction
 Lateral instability repair/reconstruction
 Achilles instability repair/reconstruction
 Midfoot reconstruction
 Hallux valgus reconstruction

Pelvis

Bladder neck suspension procedures

Predicate Device(s): The Multitak 6.0 mm Absorbable Anchor System suture anchor implants are similar in intended use and materials to current commercially available poly-L-lactic acid absorbable implants including the Stryker BioZip Suture Anchor. The Multitak 6.0 mm Absorbable Anchor System suture anchor implants are similar in design and intended use to existing Multitak suture anchors determined to be substantially equivalent by FDA.

Predicate Comparison: Performance testing comparing the mechanical strengths and failure modes of the Multitak 6.0 mm Absorbable Anchor System suture anchor implants to predicate devices demonstrated that the anchors are statistically equivalent.

Submitted by:



Patrick Balsmann, MBA, MS, RAC
Director, Regulatory/Clinical Affairs & QA



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

Mr. Patrick Balsmann, MBA, MS, RAC
Director, Regulatory/Clinical Affairs & AQ
Bonutti Research, Inc.
P. O. Box 1367
Effingham, Illinois 62401

Re: K052799
Trade/Device Name: Multitak 6.0 mm Absorbable Anchor System
Regulation Number: 21 CFR 888.3030
Regulation Name: Fastener, Fixation, Biodegradable, Soft Tissue
Regulatory Class: II
Product Code: MAI
Dated: December 05, 2005
Received: December 06, 2005

Dear Mr. Balsmann:

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.

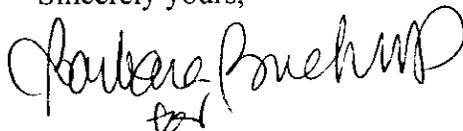
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

Mark N. Melkerson

Acting 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): K052799

Device Name: Multitak 6.0 mm Absorbable Anchor System

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- Ulnar collateral ligament reconstruction
- Radial collateral ligament reconstruction
- Biceps tendon reattachment

Knee:

- Extra-capsular repairs
 - Medial collateral ligament repair
 - Lateral collateral ligament repair
 - Posterior oblique ligament repair
- Illiotalibial band tenodesis
- Patellar tendon repair
- VMO advancement
- Joint capsule closure

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- Medial instability repair/reconstruction
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- Achilles instability repair/reconstruction
- Midfoot reconstruction
- Hallux valgus reconstruction

Pelvis

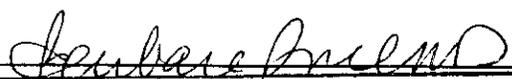
- Bladder neck suspension procedures

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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


(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)
**Division of General, Restorative,
and Neurological Devices**

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