

**Bonutti Research, Inc. – Multitak SS™ Bone Anchor
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, MS, RAC,
Manager, QA & Regulatory/Clinical Affairs
Bonutti Research, Inc.,
P.O. Box 1367, Effingham, Illinois 62401
Phone: 217.342.3412, ext. 321

Date Prepared: September 13, 1999

Proprietary Name: Multitak SS™ Bone anchor

Common Name: Soft Tissue Anchor

Classification Name: Unclassified.

Device Description: Multitak SS™ bone anchors are cylindrical suture anchors with an overall ratio of approximately 2:1, length to diameter. The suture anchors are processed from human cortical bone and provided sterile and are intended for single use. The bone soft tissue anchors with attached suture are inserted into a predrilled bone hole site with a single use disposable or a reusable introduction device. The suture ends are pulled to engage cancellous bone and to toggle and lock the anchor in bony tissue. A curved needle attached to the suture end(s) is used to secure soft tissue to bone.

Intended Use: The Multitak SS™ bone anchors are intended for use as load bearing or non-load bearing suture anchors in the attachment of soft tissue to bone in various orthopedic surgical procedures. The bone anchors are provided sterile and are intended for single use with suture up to USP Size No. 2.

Multitak SS™ bone anchors are indicated for use in the following orthopedic soft tissue to bone fixation applications:

Shoulder: Bankart lesion repairs
S.L.A.P. lesions repairs
Acromio-clavicular repairs
Capsular shift/capsulolabral reconstruction
Deltoid repairs
Rotator cuff tear repairs
Biceps tenodesis

Bonutti Research, Inc. – Multitak SS™ Bone Anchor
510(k) Summary of Safety and Effectiveness
Page 2

Elbow: Biceps tendon reattachment
Tennis elbow repair
Ulnar or radial collateral ligament reconstruction

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

Foot/Ankle: Medial/Lateral repairs/reconstructions
Achilles tendon repairs
Midfoot and forefoot repairs
Hallus valgus reconstruction

Hand/Wrist: Collateral ligament repair (Gamekeeper’s Thumb)
Scapholunate ligament reconstruction
Tendon transfers in phalanx
Volar plate reconstruction

Predicate Device: The Multitak SS™ bone anchors are similar in intended use and design to Multitak SS™ titanium suture anchors (K973015.) The bone anchors method of insertion with disposable or reusable introduction devices is similar in design and materials to currently marketed Multitak SS™ introduction devices (K973015 and K934183.) Performance testing comparing the pullout strengths and failure modes of Multitak SS™ cortical bone anchors to titanium anchors demonstrated that the anchors were statistically equivalent.

Predicate Comparison: A chart comparing characteristics of the Multitak SS™ bone anchors to those of the predicate devices is attached.

Submitted by:



Patrick Balsmann
Manager, QA & Regulatory/Clinical Affairs

Bonutti Research, Inc. – Multitak SS™ Bone Anchor
510(k) Premarket Notification
Substantial Equivalence Chart

Device Characteristic	Multitak SS™ Bone Anchor	Multitak SS™ Titanium Anchor	Multitak SS™ Stainless Steel Anchor
510(k) Number	Current Submission.	K973015.	K934183.
Intended Use	Orthopedic procedures involving the attachment of soft tissue to bone.	Orthopedic procedures involving the attachment of soft tissue to bone.	Orthopedic procedures involving the attachment of soft tissue to bone.
Indications For Use	Shoulder, elbow, knee, foot/ankle, and hand/wrist soft tissue to bone orthopedic procedures.	Shoulder, elbow, knee, foot/ankle, and hand/wrist soft tissue to bone orthopedic procedures.	Shoulder, elbow, knee, and foot/ankle soft tissue to bone orthopedic procedures.
Anchor Design	Cylindrical anchors approximate ratio of 2:1 length to diameter.	Cylindrical anchors approximate ratio of 2:1 length to diameter.	Tubular anchors approximate ratio of 2:1 length to diameter. Single and double anchor tube constructs.
Anchor Material	Allograft human cortical bone.	Titanium.	Stainless steel.
Anchor Insertion Method	Anchor with threaded suture loaded on to tip of disposable or reusable introduction device.	Anchor with threaded suture loaded on to tip of disposable introduction device.	Anchor with threaded suture loaded on to tip of reusable introduction device.
Anchor Provided Sterile	Sterile.	Sterile.	Sterile.
Anchor Packaging	One individual anchor preloaded in disposable introduction device. One individual anchor.	One individual anchor preloaded in disposable introduction device.	One individual anchor preloaded in disposable introduction device. One individual anchor.

K993115
3 of 3



DEC 17 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Patrick G. Balsmann, MS, RAC
Manager, QA & Regulatory/Clinical Affairs
Bonutti Research, Incorporated
P.O. Box 1367
2600 South Raney
Effingham, Illinois 62401

Re: K993115
Trade Name: Multitak SS™ Bone Anchor
Regulatory Class: II
Product Code: MAI and JDW
Dated: September 17, 1999
Received: September 20, 1999

Dear Mr. Balsmann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

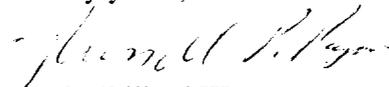
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. Patrick G. Balsmann, MS, RAC

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



gcr James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

