K990156

Bonutti Research, Inc. – Multitak SS Buttons
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/RA & Clinical
Bonutti Research, Inc.,
P O Box 1367, Effingham, Illinois 62401
Phone 217 342 3412 ext 321

Date Prepared: March 1, 1999

Proprietary Name: Multitak SS Buttons

Common Name: Fracture Fixation Device and Surgical Buttons.

Classification Name: 21 CFR 888 3040 Smooth Or Threaded Metallic Bone Fixation Fastener and 21 CFR 878 4930 Suture Retention Device

Device Description: The Multitak SS Buttons are fixation devices indicated in orthopedic fracture and in ligament and tendon repair. They are intended to stabilize two or more bone fragments and distribute suture tension over the fracture site in order to facilitate healing. The buttons also serve as fixation posts for distributing suture tension over areas of ligament and tendon repair. The cylindrical buttons are made from titanium, polypropylene, or polyethylene and have an overall ratio of approximately 3:1, length to diameter. The buttons are available in the following sizes: (1) 1.2 mm in diameter and 4.0 mm in length, (2) 1.8 mm in diameter and 6.9 mm in length, (3) 2.5 mm in diameter and 8.3 mm in length, and (4) 3.0 mm in diameter and 10.3 mm in length. The buttons are applied to the outer bone cortex over a predrilled hole across the fracture site. Bone fragments are stabilized with suture running through the drill bone hole and tied off at the button. The buttons provide linear fixation and compression of the bone fragments promoting healing at the fracture site. Buttons can also be used as fixation posts and are placed outside the cortical bone in ligament and tendon repair. They provide a means of distributing suture tension over areas of repaired ligaments and tendons. The buttons are provided sterile with or without attached suture in packs of two and are not intended for reuse.

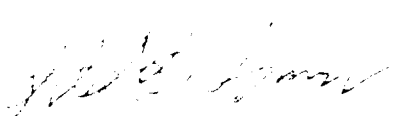
Intended Use: The Multitak SS Buttons are new fixation devices indicated in orthopedic fracture and in ligament and tendon repair. The buttons allow for stabilization and linear fixation of bone fragments in fracture procedures. The buttons also serve as fixation posts for distributing suture tension over areas of ligament and tendon repair. The buttons are made of titanium, polypropylene, or polyethylene and are provided sterile with or without suture attached and are not intended for reuse. Maximum suture size to be used with each of the buttons are outlined in the following table

Multitak SS Button Size	Button Material	Maximum USP Suture Size
3.0 mm x 10.0 mm	Ti-6Al-4V	Up to USP Size 2
3.0 mm x 10.0 mm	Polypropylene	Up to USP Size 2
3.0 mm x 10.0 mm	Ultra-high-molecular-weight polyethylene (UHMWPE)	Up to USP Size 2
[illegible] mm x 8.3 mm	Ti-6Al-4V	Up to USP Size 2
[illegible] mm x 8.3 mm	Polypropylene	Up to USP Size 1
[illegible] mm x 8.3 mm	UHMWPE	Up to USP Size 1
1.8 mm x 6.0 mm	Ti-6Al-4V	Up to USP Size 2
[illegible] mm x 4.0 mm	Ti-6Al-4V	Up to USP Size 2-0

Predicate Device: The Multitak SS Buttons are similar in intended use to Kirschner Wires and Steinmann Pins manufactured by Synvasive Technology, Inc. (K961522) and to Ethicon, Inc., Polypropylene Buttons regulated as Class I surgical buttons. The Multitak SS Buttons are similar in design and materials to the Multitak SS™ Suture System soft tissue suture anchor devices manufactured by Bonutti Research, Inc. (K973015 and K964532.)

Predicate Comparison: A chart comparing characteristics of the The Multitak SS Buttons to those of the predicate devices is attached

Submitted by:



Patrick Balsmann
Manager, QA/RA & Clinical

Device Characteristic	MultiTak SS Buttons	Synthes Technology, Inc. Kirschner Wires and Steinmann Pins	Ethicon, Inc. Polypropylene Surgical Buttons	MultiTak SS™ Suture System – Titanium Soft Tissue Anchor	MultiTak SS™ Suture System – UHMWPE Soft Tissue Anchor
510(k) Number	Current Submission	K961522	Class I	K973015	K964532
Intended Use	Stabilize two or more bone fragments by distributing suture tension over fracture site	Draw two or more bone fragments together to facilitate healing	Aid wound healing by distributing suture tension over contact surface area	Soft tissue to bone suture fixation	Soft tissue to bone suture fixation
Indications	Bone fracture repair Ligament and tendon repair	Bone fracture repair	Orthopedic tendon repair	Shoulder, elbow, knee, foot/ankle, and hand/wrist soft tissue to bone orthopedic applications	Shoulder, elbow, knee, and foot/ankle, soft tissue to bone orthopedic applications
Design	Tubular buttons approximate ratio of 3:1 length to diameter.	Sized K-wires and pins	14 mm diameter round buttons.	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
Material	Titanium (Ti-6Al-4V) alloy; polypropylene; and polyethylene (UHMWPE.)	Stainless steel.	Polypropylene.	Titanium (Ti-6Al-4V) alloy and stainless steel.	Polyethylene (UHMWPE.)
Provided Sterile	Sterile.	Sterile and non-sterile.	Sterile.	Sterile.	Sterile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 1999

Patrick G. Balsmann, M.S., RAC
Manager, QA/RA and Clinical Affairs
Bonutti Research, Inc.
P.O. Box 1367
Effingham, Illinois 62401

Re: K990156
Multitak SS Button
Regulatory Class: II
Product Codes: MBI and GAT
Dated: January 14, 1999
Received: January 19, 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 (Premarket 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.

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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K990156

Bonutti Research, Inc. – Multitak SS Buttons
510(k) Premarket Notification

INDICATIONS FOR USE

Device Name: Multitak SS Buttons.

Indications for Use: The Multitak SS Buttons are new fixation devices indicated in orthopedic fracture and in ligament and tendon repair. The buttons allow for stabilization and linear fixation of bone fragments in fracture procedures. The buttons also serve as fixation posts for distributing suture tension over areas of ligament and tendon repair. The buttons are made of titanium, polypropylene, or polyethylene and are provided sterile with or without suture attached and are not intended for reuse. Maximum suture size to be used with each of the buttons are outlined in the following table:

Multitak SS Button Size	Button Material	Maximum USP Suture Size
3.0 mm x 10.0 mm	Ti-6Al-4V	Up to USP Size 2
3.0 mm x 10.0 mm	Polypropylene	Up to USP Size 2
3.0 mm x 10.0 mm	Ultra-high-molecular-weight polyethylene (UHMWPE)	Up to USP Size 2
2.5 mm x 8.3 mm	Ti-6Al-4V	Up to USP Size 2
2.5 mm x 8.3 mm	Polypropylene	Up to USP Size 1
2.5 mm x 8.3 mm	UHMWPE	Up to USP Size 1
1.8 mm x 6.0 mm	Ti-6Al-4V	Up to USP Size 2
1.2 mm x 4.0 mm	Ti-6Al-4V	Up to USP Size 2-0

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990156