Multitak SS
FROM BONUTTI RESEARCH

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FEB 25 2004

Bonutti Research, Inc., - TranSet™ Fracture Fixation System
510(k) Premarket Notification
February 24, 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

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

Date Prepared: November 25, 2003

Proprietary Name: TranSet™ Fracture Fixation System.

Common Name: Trauma Fracture Fixation System.

Classification Name: 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener and 21 CFR 878.4930 Suture retention device.

Device Description: The TranSet™ Fracture Fixation System intended use is in the stabilization and linear fixation of bone or tissue fragments in orthopedic fractures and in ligament and tendon repair and reconstruction. The system consists of both absorbable and titanium cylindrical buttons manufactured from poly-L-lactic acid or titanium alloy. The buttons are provided sterile packaged with or without braided suture and are intended for single-patient use. Buttons are applied to the outer bone cortex and with suture running across the fracture site allows for stabilization and linear fixation of the bone or tissue fragments. This allows the bone or tissue fragments to be compressed and held together to promote healing. The cylindrical design of the buttons also allows them to be used as fixation devices in orthopedic ligament and tendon repair and reconstruction. The buttons are placed outside the cortical bone or though a soft tissue repair site and act as fixation posts by distributing suture tension over larger areas to promote healing and eliminate any suture tearing or pulling through the tissue. The absorbable buttons degrade over time and eliminate the need for any surgical removal. Removal of the titanium buttons is based upon surgeon preference. Reusable manual surgical instrumentation for insertion of the buttons and a sterilization tray for autoclaving complete the system.

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Indications for Use: The TranSet™ Fracture Fixation System is indicated as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated. It may also be used as an adjunct to external and intramedullary fixation systems involving fixation plates and rods, with fracture braces and casting, and with bone graft substitutes. The system is also indicated in ligament and tendon repair and reconstruction associated with fractures and soft tissue reattachment including ligament/tendon avulsions and meniscal repairs. The system consists of both absorbable and titanium fixation buttons used with up to USP Size No. 5-braided suture and are not intended for reuse. The system may also be used with the Unity Ultrasonic Fixation seat for tissue approximation and ligation when using USP Size No. 2-0 through 2-braided suture. Custom manual surgical instrumentation for button insertion and a sterilization tray complete the TranSet™ Fracture Fixation System.

The TranSet™ Fracture Fixation System is not indicated for use in intra-articular sites.

Predicate Device (s): The TranSet™ Fracture Fixation System is similar in intended use and materials to the Multitak SS Buttons (K990156), Linvatec, Corp., BioButton™ (K990194) and Inion, Ltd., OTPS™ Biodegradable pins (K031712). The TranSet™ Fracture Fixation System buttons are also similar in design and materials to the Multitak SS Buttons and the Multitak Splinter 3.0 mm Resorbable Anchors (K012456).

Predicate Comparison: Performance testing comparing the mechanical strengths and failure modes of the TranSet™ Fracture Fixation System absorbable and titanium buttons to stainless steel Steinmann Pins commonly used in fracture fixation procedures demonstrated the buttons are statistically equivalent.

Submitted by:

Patrick G. Balsmann, 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

FEB 25 2004

Mr. Patrick G. Balsmann, MS, RAC
Director, Regulatory/Clinical Affairs and Quality Assurance
Bonutti Research, Inc.
P.O. Box 1367
Effingham, Illinois 62401

Re: K033717
Trade/Device Name: TranSet™ Fracture Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: November 25, 2003
Received: November 28, 2003

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 (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for Mark N. Milham

Celia M. Witten, Ph.D., M.D.
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): K033717

Device Name: TranSet™ Fracture Fixation System.

Indications For Use:

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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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhem

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

510(k) Number K033717