K971144 JUN 25 1997

Summary of Safety and Effectiveness
***Multitak* Suture System™**

- **Submitted by**

  Bonutti Research, Inc.
  1303 Evergreen Ave.
  Effingham, IL 62401

- **Prepared by**

  Lynnette Whitaker
  Director
  Regulatory Affairs/Quality Assurance

- **Date**

  June 24, 1997

- **Trade Name**

  Multitak Suture System

- **Common Name**

  Soft Tissue Anchor

- **Classification Name**

  21 CFR 888.3040, Smooth or Threaded Metallic Bone Fixation Fastener

- **Predicate Devices**

  - *Multitak* SS Suture System, manufactured by Bonutti Research, K934183.
  - GII Anchor System, manufactured by Mitek Surgical Products, Inc., K953877.
  - Mini QuickAnchor, manufactured by Mitek Surgical Products, Inc., K930892 and K904436.
  - Statak Soft Tissue Attachment Device, manufactured by Zimmer, Inc., K926384, cleared November 16, 1993 and K962397, cleared August 27, 1996.

- **Device Description**

The anchor is tubular in shape and is preassembled threaded with USP size 2-0 through 2 braided polyester suture. An Introduction Device holds the anchor and delivers it into the bone through a predrilled hole. The sutures can then be used to secure the soft tissue to the bone.

- **Intended Use**

The devices are intended for soft tissue to bone suture fixation for the following indications:

Shoulder
- Bankart lesion repairs
- S.L.A.P. lesion repairs
- Acromio-clavicular Repairs
- Capsular Shift/Capsulolabral Reconstruction
- Deltoid Repair
- Rotator cuff tear repairs
- Biceps tenodesis

Foot and Ankle
- Medial/lateral repairs, reconstructions
- Achilles tendon repairs
- Midfoot and forefoot repairs
- Hallux Valgus reconstruction

Elbow
- Ulnar or radial collateral ligament reconstructions
- Tennis elbow repair
- Biceps tendon reattachment

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

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

- **Performance Data**

The *Multitak* Suture System was compared in pullout testing to the predicate device and found to demonstrate pullout strengths superior to those of a suture only reattachment technique. Insertion testing was performed to verify insertion and locking at all indicated sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Lynnette Whitaker, RAC
Director, Regulatory Affairs/Quality Assurance
Bonutti Research, Inc.
1303 Evergreen Avenue
Effingham, Illinois 62401

JUN 25 1997

Re: K971144
Multitak SS Suture System®
Regulatory Class: II
Product Codes: MBI and HWC
Dated: March 27, 1997
Received: March 28, 1997

Dear Ms. Whitaker:

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,

Marie A. Schroeder MS, PT

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

510(k) Number (if known): K971144

Device Name: MULTITAK SUTURE SYSTEM

Indications For Use:

The Multitak Suture System is intended for soft tissue to bone suture fixation for the following indications:

Shoulder
Bankart lesion repairs
S.L.A.P. lesion repairs
Acromio-clavicular repairs
Capsular shift/capsulolabral reconstruction
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(Gamekeeper's Thumb)
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Hand/Wrist
Collateral ligament repair
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Tendon transfers in phalanx
Volar plate reconstruction

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marie A. Schroeder MS PT for CMW.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971144

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)