zimmer

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Summary of Safety and Effectiveness

Resorbable Soft Tissue Attachment Device, 5.0 mm Diameter

- **Submitted by**

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- **Prepared by**

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- **Date**

  May 8, 1996

- **Trade Name**

  Resorbable Soft Tissue Attachment Device

- **Common Name**

  Resorbable Soft Tissue Anchor

- **Classification Name**

  None Assigned

- **Predicate Devices**

  - Resorbable Soft Tissue Attachment Device manufactured by Zimmer
  - *QuickAnchor*™ manufactured by Mitek

- *Bio-Anchor*™ Absorbable Suture Anchor manufactured by Linvatec

- *Statak*® Soft Tissue Attachment Device manufactured by Zimmer

- **Device Description**

The RSTA device is manufactured using poly (L-lactic) acid in a proprietary process. The anchor is a fully threaded device 12 mm in length and 5.0 mm in diameter. The anchor contains an eyelet to which a USP Size No. 2 braided polyester nonabsorbable suture and two suture needles are attached. A hex drive at the proximal end of the anchor attaches to a disposable torque limiting driver used for insertion of the anchor. The anchor requires predrilling and tapping procedures prior to implantation. Following implantation of the anchor, the free ends of the suture are used to reattach the soft tissue to the bony site.

- **Intended Use**

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

Shoulder
- Bankart lesion repairs
- SLAP lesion repairs
- Acromio-clavicular separations repairs
- Rotator cuff tear repairs
- Capsular shift or capsulolabral reconstructions
- Biceps tenodesis
- Deltoid repairs

Foot and Ankle
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Hallux valgus reconstructions

Elbow, Wrist, and Hand
- Scapholunate ligament reconstructions
- 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 repairs

- **Performance Data**

  The RSTA device was tested for pullout strength in dry white pine wood and in varying types of porcine bone. The RSTA device demonstrated strength far above that of the No. 2 suture used clinically with the device, thereby ensuring that the suture will fail prior to any portion of the anchor. Pullout testing in white pine wood and porcine bone also demonstrated superior pullout strength when compared to the predicate devices.

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