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Summary of Safety and Effectiveness *Multitak Suture System™*

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- **Submitted by**

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- **Date**

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- **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.

- **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

- Rotator cuff tear repairs
- Biceps tenodesis

Foot and Ankle

- Lateral instability repairs/reconstructions

Elbow, Wrist and Hand

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

Knee

- Extra-capsular repairs:
 - Medial collateral ligament
 - Lateral collateral ligament

- **Performance Data**

The nature of device changes do not necessitate performance data testing.