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**SUMMARY OF SAFETY AND EFFECTIVENESS  
MITEK MICRO ANCHOR**

**SUBMITTER:**

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**NAME OF DEVICE**

**CLASSIFICATION NAME:** Staple, Fixation, Bone  
**COMMON NAME:** Appliance for reconstruction of bone to soft tissue  
**PROPRIETARY NAME:** MITEK MICRO ANCHOR

**PREDICATE DEVICE: SUTURE**

**DESCRIPTION OF DEVICE**

**FUNCTION**

Fixation of USP #4/0 suture below bone surface.

**DEVICE DESIGN**

The Mitek Micro Anchor is 3.7mm in length by 1.3mm in diameter. It is manufactured from Titanium 6Al 4V and uses a Nitinol arc. It is similar in design to the Mitek GII Mini Anchor. The same methods of manufacturing and assembly are used for the Micro Anchor as those used for manufacturing all other Mitek metal anchors. The Mitek Mini anchor design was first cleared to market by US FDA in K915089 and K930892.

**MATERIAL USED**

The Mitek Micro Anchor delivery system consists of a Mitek Micro Anchor, a drill bit, and an Insertor.

**INTENDED USE**

The device is used to anchor suture into bone. The suture is subsequently used by the surgeon to reattach the repositioned/injured soft tissue to bone. The purpose of this 510(k) submission is to obtain clearance for the Mitek Micro Anchor for the lateral canthoplasty and collateral ligament(s) around the (PIP) joint. The intended use is the same as the predicate device, i.e., suture, when used to approximate soft tissue to bone during a period of rehabilitation.

**COMPARISON TO PREDICATE DEVICE**

It has greater strength than USP #4/0 suture, and is the same "design" as the Mitek Mini Anchor.

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#### DESCRIPTION OF NON CLINICAL TESTS

The MitekMicro Anchor pull tests from cadaveric and porcine locations produced an average failure load (LBS) of:

1) CADAVER HAND	9.67, SD 1.32
2) CADAVER SKULL	7.97, SD 1.92
3) PIG METACARPALS	7.28, SD 0.72
4) SUTURE W/ BONE TUNNELS	5.73, SD 0.46

USP Class I knot pull synthetic sterilized #4/0 suture, double strand, single knot, is 2.64 lbs.

Suture tissue failure for tendinous tissue is 15.75 lbs, and capsular tissue is 21.80 lbs. Reference: Soft Tissue Fixation to Bone, Daniel B. Robertson, M.D. et al, The American Journal of Sports Medicine, Vol. 14, No. 5, 1986.

#### DESCRIPTION OF CLINICAL TESTS

The clinical tests were done in accordance with IDE #G880026. Safety and effectiveness was based upon the results obtained in the clinical trials and their equivalence to historical data for the identical surgical procedure.