

K961094
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**SUMMARY OF SAFETY AND EFFECTIVENESS
MITEK THREADED 2.0mm 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 THREADED ANCHOR

PREDICATE DEVICE: MITEK THREADED ANCHOR

DESCRIPTION OF DEVICE

FUNCTION

Fixation of USP #2/0 suture below bone surface.

DEVICE DESIGN

The Mitek Threaded Anchor is a threaded design, 2.0 mm in diameter and 3.6 mm in length. It is manufactured from Titanium 6Al 4V. It is similar in design to the 3.0mm, 4.0mm and the 5.2mm Mitek Threaded Anchor. These designs were cleared to market in K945203.

MATERIALS USED

The Mitek Threaded Anchor delivery system consists of a Mitek Threaded Anchor Tab, a drill bit ,and an Inserter.

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 expand the indications to include the browlift procedure. 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 #2/0 suture, and is the same design as the Mitek 3.0mm, 4.0mm and 5.2mm Mitek Threaded Anchors.

DESCRIPTION OF NON CLINICAL TESTS

The Mitek Threaded Anchor pull tests from cadaveric locations produced an average failure load of 32.7 lbs, SD 1.9, N=30.

USP knot pull synthetic sterilized suture, double strand, is 6.34 lbs.

Suture tissue failure 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.

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