

APR 18 1996

510(K) SUMMARY



Li Medical

Device Sponsor: Li Medical, 4 Armstrong Road, Shelton, CT 06484,
203-944-2800

Contact: Rhodemann Li, Vice President

Date: December 31, 1995

Classification Name: Staple, Fixation, Bone

Common Name: Bone anchor

Proprietary Name: LM Anchor or other proprietary name

Predicate Devices: Mitek Surgical Products GII Anchor (K915889)
Mitek Surgical Products SuperAnchor (K920213?)
Li Medical Bone Anchor (K951233)

Device Description: Made from surgical grade stainless steel (316L), the LM Anchor is designed with a crown and a center pin through which suture is passed to provide a means for soft tissue to bone attachment.

Intended Use: Shoulder (bankart repair, rotator cuff repair, SLAP lesion, acromio-clavicular separation, biceps tenodesis, deltoid repair, capsular shift reconstruction, capsulolabral reconstruction), Hand/Wrist (ulnar or lateral collateral ligament reconstruction, radial collateral ligament, scapholunate ligament reconstruction), Foot/Ankle (hallux valgus reconstruction, midfoot reconstructions, lateral stabilization, medial stabilization, achilles tendon), Elbow (biceps tendon, tennis elbow, ulnar collateral ligament, radial collateral ligament), Knee (medial collateral ligament, lateral collateral ligament, patellar tendon, patellar ligament avulsions, posterior oblique ligament, joint capsule to tibia, iliotibial band tenodesis).

Technical Comparison: The LM Anchor is similar to the Mitek anchors in its cylindrical shape, however, the bony purchase is accomplished by the LM Anchor through cantilevered beams versus nitinol arcs with the Mitek anchors.

Performance Data: Pre-clinical testing in cadaver specimen showed that the mean pullout strength of the LM Anchor was substantially equivalent to the mean pullout strength of the Mitek anchors.