

NOV 12 1996

K963812  
1 of 2

### 510(K) SUMMARY

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

**Contact:** Rhodemann Li, Vice President

**Date:** October 30, 1996

**Classification Name:** Staple, Fixation, Bone

**Common Name:** Bone anchor

**Proprietary Name:** LM Anchor Products or other proprietary names

**Predicate Devices:** Mitek Surgical Products GII QuickAnchor (K904436)  
Li Medical Bone Anchor (K951233), (K951472),  
(K953764), (K960448), (K960439), (K960825)

**Device Description:** Made from surgical grade stainless steel (316L) or titanium (6Al-4V ELI), the LM Anchor Products are 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:**

**UltraFix RC** Shoulder (rotator cuff repair)

**UltraFix Mini** 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, ulnar collateral ligament, radial collateral ligament)

**UltraFix** 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, 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 Products are similar to the Mitek anchors in its cylindrical shape, however, the bony purchase is

accomplished by the LM Anchor Products 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 Products were substantially equivalent to the mean pullout strength of the Mitek anchors.