

K 981764

JUL 13 1998

510(K) SUMMARY

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

Contact: Rhodemann Li, Vice President

Date: May 18, 1998

Classification Name: Staple, Fixation, Bone

Common Name: Bone anchor

Proprietary Name: LM Anchor or other proprietary name

Predicate Device: Mitek Surgical Products Mini Anchor (K930892)

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), Hand/Wrist (ulnar or lateral collateral ligament reconstruction, scapholunate ligament reconstruction, PIP collateral ligament, profundus tendon reattachment), Skull (lateral canthoplasty), Foot/Ankle (hallux valgus reconstruction, midfoot reconstructions.

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 or exceeded the mean pullout strength of the Mitek anchor.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 13 1998

Mr. Rhodemann Li  
Vice President  
Li Medical Technologies, Inc.  
4 Armstrong Road  
Shelton, Connecticut 06484

Re: K981764  
Trade Name: LM Anchor  
Regulatory Class: II  
Product Codes: MBI, HWC, and GAT  
Dated: May 18, 1998  
Received: May 19, 1998

Dear Mr. Li:

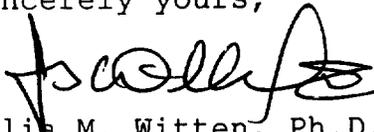
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
A Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K981764

Device Name: LM Bone Anchor

Indications For Use:

Shoulder - bankart repair

Hand/wrist - ulnar or lateral collateral ligament reconstruction, scapholunate ligament reconstruction, PIP collateral ligament, profundus tendon reattachment

Skull - lateral canthoplasty

Foot/ankle - hallux valgus reconstruction, midfoot reconstructions

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Director Sign-Off)  
D. General Administrative Services  
510(k) number K981764

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)