

JUL 13 1998

K981755

510(K) SUMMARY

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

Contact: Rhodemann Li, Vice President

Date: May 15, 1998

Classification Name: Staple, Fixation, Bone

Common Name: Bone anchor

Proprietary Name: LM Anchor or other proprietary name

Predicate Device: Mitek Surgical Products GII Anchor (K915889)

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, 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 or exceeded the mean pullout strength of the Mitek anchor.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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: K981755
Trade Name: LM Anchor
Regulatory Class: II
Product Codes: MBI, HWC, and GAT
Dated: May 15, 1998
Received: May 18, 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.

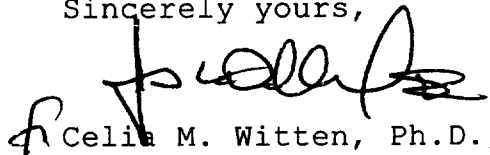
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Rhodemann Li

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 handwritten signature in black ink, appearing to read 'Celia M. Witten', is written over the typed name.

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): K981755

Device Name: LM Bone Anchor

Indications For 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

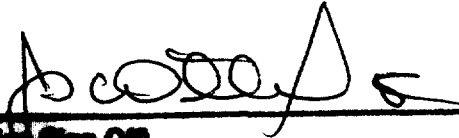
Foot/ankle - hallux valgus reconstruction, midfoot reconstructions, lateral stabilization, medial stabilization, achilles tendon

Elbow - biceps tendon, 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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981755

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)