10/13/2022

LB Medical L.L.C.
Terry Sheridan Powell
Senior Project Manager
901 King Street, Suite 200
Alexandria, Virginia 22314

Re: K080158
Trade/Device Name: LB Medical Inflatable Tissue Elevator/Expander System
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: Class I
Product Code: FZW

Dear Terry Sheridan Powell:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 3, 2008. Specifically, FDA is updating this SE Letter because FDA has better categorize your device technology under product code FZW.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Deborah Fellhauer, OHT4: Office of Surgical and Infection Control Devices, 301-796-9570, Deborah.Fellhauer@fda.hhs.gov.

Sincerely,
Deborah A. Fellhauer -S
Deborah A. Fellhauer -S
2022.10.13 13:11:01
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Deborah A. Fellhauer RN, BSN
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2008

LB Medical LLC
% M Squared Associates, Inc.
Terry Sheridan Powell
901 King Street, Suite 200
Alexandria, Virginia 22314

Re: K080158
Trade/Device Name: The LB Medical Inflatable Tissue Elevator/Expander System
Regulatory Class: Unclassified
Product Code: LCJ
Dated: April 15, 2008
Received: April 16, 2008

Dear Terry Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K 080158

Device Name: The LB Medical Inflatable Tissue Elevator/Expander System

Indications for Use:

The LB Medical Inflatable Tissue Elevator/Expander System is a surgical tool intended for use as a conventional manual elevator for orthopaedic or general surgery, including use to access the carpal tunnel region during carpal tunnel release procedures.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for mxm

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K080158

K080158

MAY - 2 2008

# Section 5: 510(k) Summary

| | |
|---|---|
| Sponsor's Name, Address, Phone & Fax: | LB Medical, LLC<br>895 Mohawk Road<br>Franklin Lakes, NJ 07417 |
| Contact Person: | Terry Sheridan Powell<br>M Squared Associates, Inc., Consultants to LB Medical, LLC<br>(T) 703-562-9800<br>(F) 703-562-9797<br>tpowell@msquaredassociates.com |
| Date Prepared: | January 18, 2008 |
| Device Trade Name | LB Medical Inflatable Tissue Elevator/Expander System |
| Device Common Name: | Elevator |
| Proposed Class, Classification Name and Number, and Product Code: | Class I (non-exempt)<br>878.4800 - Manual surgical instrument for general use<br>HTE – Elevator |
| Predicate Devices: | • Preamendment: Elevator/Probe/Groove Director/Freer<br>• K041454: KyphX Inflatable Bone Tamp<br>• K061903: Acclarent Sinus Balloon Catheter<br>• K972109: Spacemaker Surgical Balloon Disssector/Expander<br>• K061937: Cook Esophageal Dilation Balloon |
| Device Description : | The subject device is similar to a traditional elevator, but features a manually inflatable balloon component at the distal end. The balloon is inflated/deflated with saline via a manual inflation syringe system with an integral pressure gauge. |
| Intended Use: | The LB Medical Inflatable Tissue Elevator/Expander System is a surgical tool intended for use as a conventional manual elevator for orthopaedic or general surgery, including use to access the carpal tunnel region during carpal tunnel release procedures. |
| Summary of Technological Characteristics: | The main technological characteristics of the subject device include:<br>• A traditional manual elevator: the subject device features a thin grooved metal probe (also called an elevator, grooved director, or freer). As with the predicate KyphX device, this probe houses an uninflated expandable balloon at its distal end.<br>• Expandable balloon: the subject device features a semi-round expandable balloon housed at the distal end of the metal elevator. The balloon is made from non-compliant material that expands unidirectionally when inflated. The manually inflatable balloon feature is shared by all the cited post- |

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| | amendment 510(k)-cleared predicate devices.<br>• Balloon expansion mechanism: the subject device's balloon component is expanded with saline manually using a syringe/catheter assembly with an integral pressure gauge. This feature is shared by several of the cited post-amendment predicate devices. |
| Summary of nonclinical tests | Biocompatibility tests on the balloon material have demonstrated the suitability of the material for its intended purpose. Bench testing of the balloon has demonstrated that its performance characteristics are suitable for its intended use during hand surgery. |
| Summary of clinical tests | Clinical testing was not required to demonstrate the substantial equivalence of the subject device to its predicate devices with regard to materials, design, technological characteristics, or intended use. |
| Conclusions from nonclinical and clinical tests | The subject device features materials that are suitable for the device's intended purpose. The device's balloon mechanism is suitable for its intended uses during hand surgery. |

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**510(k) Number** K080158