

510(k) SUMMARY
ConMed Linvatec Soft Tissue to Bone System

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec is hereby submitting the 510(k) Summary of Safety and Effectiveness for the 510(k) Number K091549.

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

JUN 23 2009

B. Company Contact

John Cusack
Regulatory Affairs Specialist
(727) 399-5562 Telephone
(727) 399-5264 FAX

C. Device Name

| | |
|------------------------|--|
| Trade Name: | <i>ConMed Linvatec Soft Tissue to Bone System</i> |
| Common Name: | Nonabsorbable suture anchor system |
| Classification Name: | Fastener, Fixation, Nondegradable, Soft tissue |
| Proposed Class/Device: | Class II |
| Product Code: | MBI |
| Regulation: | 21 CFR Part 888.3040 |

D. Predicate/Legally Marketed Devices

| | |
|---------------|--|
| Device Name: | LM Bone Anchor (renamed ConMed Linvatec Ultrafix RC [®]) |
| Company Name: | Li Medical Technologies Inc (purchased by ConMed Linvatec) |
| 510(k) #: | K963812 |

| | |
|---------------|---|
| Device Name: | ThRevo [®] Anchor, Disposable Driver, Hi-Fi [™] Sutures |
| Company Name: | ConMed Linvatec |
| 510(k) #: | K073481 |

| | |
|---------------|--|
| Device Name: | ConMed Linvatec Bio Mini-Revo [®] |
| Company Name: | ConMed Linvatec |
| 510(k) #: | K053561 |

E. Device Description

The *ConMed Linvatec Soft Tissue to Bone System* includes anchors in a range of sizes and materials from 3.5 mm to 6.5 mm diameter and 15 mm to a 17 mm length with one (1) to three (3) non-absorbable suture configurations. The anchor sizes correspond to a series of general surgical instruments such as; bone taps, bone punches, drivers, and a suture passer.

F. Intended Use/ Indications

The *ConMed Linvatec Soft Tissue to Bone System* is intended to reattach soft tissue to bone in orthopedic surgical procedures. The system may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

G. Substantial Equivalence

The *ConMed Linvatec Soft Tissue to Bone System* is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the identified predicate devices.



JUN 23 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ConMed Linvatec Corporation
c/o Mr. John Cusack
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K091549

Trade/Device Name: ConMed Linvatec Soft Tissue to Bone System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 26, 2009
Received: May 27, 2009

Dear Mr. Cusack:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

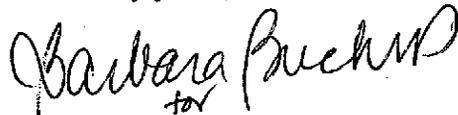
Page 2 - Mr. Cusack

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

A handwritten signature in black ink that reads "Barbara Buchner" with a small "for" written below it.

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

Enclosure

Indications for Use

510(k) Number (if known): K091549

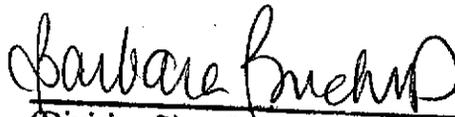
Device Name: *ConMed Linvatec Soft Tissue to Bone System*

Indications for Use:

The *ConMed Linvatec Soft Tissue to Bone System* is intended to reattach soft tissue to bone in orthopedic surgical procedures. The system may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

Prescription Use X AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091549