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JUN 22 2009

510(k) SUMMARY
ConMed Linvatec Bio Mini-Revo

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 ***K090835***.

A. Submitter

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

B. Company Contact

Joy Lovett
Regulatory Affairs Specialist
(727) 399-5137 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name:	ConMed Linvatec Bio Mini-Revo Suture Anchor
Common Name:	Bioabsorbable suture anchor
Classification Name:	Biodegradable soft tissue fixation fastener
Proposed Class/Device:	Class II
Product Code:	MAI
Regulation:	888.3030

D. Predicate/Legally Marketed Devices

Device Name:	ConMed Linvatec Bio Mini-Revo Suture Anchor
Company Name:	ConMed Linvatec
510(k) #:	K072291

Device Name:	ConMed Linvatec Bio Mini-Revo Suture Anchor
Company Name:	ConMed Linvatec
510(k) #:	K053561

Device Name:	Bio-FASTak Suture Anchor
Company Name:	Arthrex, Inc.
510(k) #:	K061863

E. Device Description

The Linvatec Bio Mini-Revo® suture anchor is a bioabsorbable screw-in suture anchor that is preloaded on a disposable inserter device with one non-absorbable, braided, polyethylene suture. The Bio Mini-Revo suture anchor is manufactured from Self-Reinforced (96L/4D) PLA Copolymer. The Copolymer is inert and non-collagenous through the absorption process. The device will be available in two versions: with or without colorant D&C violet #2.

F. Intended Use/ Indications

The device 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. Additional indications include acetabular labral repair and capsular repair in the hip.

G. Substantial Equivalence

The ConMed Linvatec Bio Mini-Revo Suture Anchor is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the identified predicate devices K053561, K072291 and K061863.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 2009

ConMed Linvatec
% Ms. Joy Lovett
Regulatory Affairs Specialist
11311 Concept Blvd.
Largo, Florida 33773

Re: K090835
Trade/Device Name: ConMed Linvatec Bio Mini-Revo Suture Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: March 23, 2009
Received: March 27, 2009

Dear Ms. Lovett:

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) 276-0120. 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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

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Indications for Use

510(k) Number (if known): **K090835**
Device Name: *ConMed Linvatec Bio Mini-Revo Suture Anchor*

Indications for Use:

The device 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. Additional indications include acetabular labral repair and capsular repair in the hip.

Prescription Use X AND/OR (Part 21 CFR 801 Subpart D)

Over-the-Counter Use_____ (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)

Mark N Milhern

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090835