AUG 2 6 2010

510(k) SUMMARY
ConMed Linvatec CrossFT™ BC Suture Anchor

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 101100 .

A. Submitter

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

B. Company Contact

John Cusack
Regulatory Affairs Manager
(727) 319-5562 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name:	***ConMed Linvatec CrossFT™ BC Suture Anchor***
Common Name:	Bioabsorbable suture anchor
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories.
Proposed Class/Device:	Class II
Product Code:	MAI
Regulation:	21 CFR Part 888.3030

D. Predicate/Legally Marketed Devices

Device Name:	ConMed Linvatec Soft Tissue to Bone System
Company Name:	ConMed Linvatec
510(k) #:	K091549
Device Name:	ConMed Linvatec Bio Mini-Revo
Company Name:	ConMed Linvatec
510(k) #:	K053561
Device Name:	ConMed Linvatec Matryx Interference Screw
Company Name:	ConMed Linvatec
510(k) #:	K052080

E. Device Description

The ***ConMed Linvatec CrossFT™ BC Suture Anchor*** is a device that is used to assist the surgeon in reattaching soft tissue to bone. The device includes anchors, manufactured of 96L/4D PLA co-polymer + β-TCP and two (2), or three (3) Hi-Fi® sutures manufactured of polyethylene and polypropylene. The device is bioabsorbable and is available in sizes between 4.5mm to 6.5mm diameter and 17mm lengths. A disposable driver is included to implant the suture anchor.

F. Intended Use/ Indications

The ***ConMed Linvatec CrossFT™ BC Suture Anchor*** 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. Contraindications

The ***ConMed Linvatec CrossFT™ BC Suture Anchor*** is contraindicated for the following orthopedic procedures:

- ACL (Anterior Cruciate Ligament), PCL (Posterior Cruciate Ligament), foot, and hand procedures

H. Substantial Equivalence

The ***ConMed Linvatec CrossFT™ BC Suture Anchor*** is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the ConMed Linvatec CrossFT PEEK Suture Anchor (K091549 - Soft Tissue to Bone System), ConMed Linvatec Bio Mini-Revo Suture Anchor (K053561), and ConMed Linvatec Matryx Interference Screw (K052080). The verification and validation testing of the ***ConMed Linvatec CrossFT™ BC Suture Anchor*** includes fixation strength, cyclic loading, insertion torque, material degradation and packaging/transportation qualification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

ConMed Linvatec
c/o Mr. John Cusack
Regulatory Affairs Manager
11311 Concept Boulevard
Largo, Florida 33773

AUG 26 2010

Re: K101100
Trade/Device Name: CrossFT BC 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: August 6, 2010
Received: August 9, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

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" (21CFR 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Suchko for

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

Enclosure

K101100

Indications for Use

510(k) Number (if known): ____K101100_____

Device Name: ***ConMed Linvatec CrossFT™ BC Suture Anchor***

Indications for Use:

The ***ConMed Linvatec CrossFT™ BC Suture Anchor*** 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, tendon, 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____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K101100