510(k) SUMMARY
ConMed Linvatec

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 K102339

Date Prepared: August 12, 2010
Date Revised: November 5, 2010

NOV 2 3 2010

A. Submitter

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

B. Company Contact

Jan Flégeau
Regulatory Affairs Manager
(727) 399-5433 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name:	***ConMed Linvatec Sequent™ Meniscal Repair Device***
Common Name:	Suture Retention Device
Classification Name:	Nonabsorbable poly(ethylene terephthalate) surgical suture.
Proposed Class/Device:	Class II
Product Code:	GAT
Regulation:	21 CFR Part 878.5000

D. Predicate/Legally Marketed Devices

Device Name:	Meniscal Cinch™
Company Name:	Arthrex Inc.
510(k) #:	K073149
Device Name:	Ultra Fast-Fix and Ultra Fast-Fix AB Meniscal Repair Systems
Company Name:	Smith & Nephew
510(k) #:	K072322

K102339

E. Device Description

The ***ConMed Linvatec Sequent™ Meniscal Repair Device*** is an all-inside meniscal repair device that sequentially deploys implants and suture. This device allows the surgeon to generate multiple stitches in order to create fixation points along a soft tissue tear. The hand held, disposable device, provided sterile for single use, is removed at the end of the repair leaving behind a suture/implant construct. The implant encompasses a cleat which retains the suture and allows the knotless feature.

F. Intended Use

The ***ConMed Linvatec Sequent™ Meniscal Repair Device*** is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repairs, including the repair of meniscal tears.

G. Testing

ConMed Linvatec conducted verification and validation testing including cyclic loading characteristics, ultimate fixation strength of meniscal repairs, functional system testing, material degradation, risk analysis and packaging/transportation qualification. Based on this testing, we have determined that the device is safe and effective and performs as well as or better than the legally marketed predicate devices identified in Section D of this summary.

H. Substantial Equivalence

The ***ConMed Linvatec Sequent™ Meniscal Repair Device*** is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the identified predicate devices.

Minor differences between the ***ConMed Linvatec Sequent™ Meniscal Repair Device*** and the predicate devices do not raise any questions concerning safety and effectiveness and have no apparent effect on the performance, function, or intended use of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ConMed Linvatec
% Ms. Jan Flegeau
Regulatory Affairs Manager
1311 Concept Boulevard
Largo, Florida 33773

NOV 23 2010

Re: K102339
Trade/Device Name: ConMed Linvatec Sequent™ Meniscal Repair Device
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly (ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT, MBI
Dated: November 19, 2010
Received: November 22, 2010

Dear Ms. Flegeau:

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 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

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 Brenner

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): K102339

Device Name: ***ConMed Linvatec Sequent™ Meniscal Repair Device***

NOV 2 3 2010

Indications for Use:

The ***ConMed Linvatec Sequent™ Meniscal Repair Device*** is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repairs, including the repair of meniscal tears.

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 K102339