ConMed Linvatec
11311 Concept Boulevard • Largo, FL 33773-4908 • 727-392-6464 • www.linvatec.com

510(k) Summary

JUL 0 2 2013

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 510(k) Number _____.

Date Prepared: 9 April 2013

A. Submitter

Linvatec Corporation d/b/a ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

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

C. Device Name

Trade Name:	Y-Knot Flex All-Suture Anchor, w/ Two #2 (5 Metric) Hi-Fi Sutures, 1.8mm
Common Name:	Non-absorbable Suture Anchor
Classification Names:	Fastener, Fixation, Nondegradable, Soft tissue
Proposed Class/Device:	Class II
Product Codes:	MBI
Regulation	21 CFR Part 888.3040

D. Predicate/Legally Marketed Devices

Device Name:	Y-Knot™ All-Suture Anchor
Company Name:	Linvatec Corporation d/b/a ConMed Linvatec
510(k) #:	K111779

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E. Device Description

The Y-Knot® All-Suture Anchors are soft-tissue fixation devices with an expandable push-in design, provided preloaded on a flexible disposable inserter for the Y1802 (double-loaded). This suture anchor is constructed of a flat suture that is interlaced longitudinally along its central width by two suture strands. The flat suture and the double loaded suture strands are folded back on themselves at the distal end of the disposable inserter. The disposable, flexible inserter has a stainless steel shaft supporting the forked shaped tip, with ABS handle, and is provided sterile, for single use. The disposable inserter device is removed at the end of the repair leaving behind an all suture construct. This device differs from the predicate in terms of the number of sutures threaded through its center (two) and in terms of the use of a flexible driver to implant the anchor.

F. Testing

The verification and validation testing of the Flexible Y-Knot All-Suture Anchor (Y1802) includes fixation strength / pull-out, cyclic loading, insertion, biocompatibility, sterilization, shelf-life and packaging/transportation.

G. Intended Use / Indications

The non-absorbable suture anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures.

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.

H. Substantial Equivalence

The Y-Knot Flex All-Suture Anchor 1.8mm (Y1802) is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the ConMed Linvatec Y-Knot® All-Suture Anchor (K111779) while raising no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 2, 2013

Linvatec Corporation d/b/a ConMed Linvatec
% Ms. Joy Lovett
Regulatory Affairs Specialist
11311 Concept Boulevard
Largo, Florida 33773

Re: K131035
Trade/Device Name: Y-KNOT® FLEX ALL-SUTURE ANCHOR, W/TWO #2 (5 metric) HI-FI SUTURES, 1.8mm
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 17, 2013
Received: May 22, 2013

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. 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 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 contact 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. 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,

Erin D Keith

For

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

Enclosure

Indications for Use

510(k) Number (if known): K131035

Device Name: Y-KNOT® FLEX ALL-SUTURE ANCHOR, W/ TWO #2 (5 metric) HI-FI SUTURES, 1.8mm

Intended Use / Indications for Use:

The device is intended to reattach soft tissue to bone in orthopedic surgical procedures. 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.

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)

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Casey L. Hanley, Ph.D.

Division of Orthopedic Devices