CONMED CORPORATION

JAN - 3 2014

510(k) Summary

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

Date Prepared: December 31, 2013

A. Submitter

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

B. Company Contact

Nyrobia Freeman
Regulatory Affairs Specialist
Telephone (727) 399-5416
Fax (727) 399-5264

C. Device Name

Trade Name:	Y-Knot® RC All-Suture Anchor w/Two and Three #2 Hi-Fi® Sutures
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® Flex All-Suture Anchor, w/two #2 (5 Metric) HI-FI® Suture, 1.8mm
Company Name:	Linvatec Corporation d/b/a ConMed Linvatec
510(k) #:	K131035

E. Device Description

The Y-Knot® RC All-Suture Anchor w/Two and Three #2 Hi-Fi® Sutures are soft-tissue fixation devices with an expandable push-in design, provided preloaded on a disposable inserter. The suture anchors are constructed of a flat suture that is interlaced longitudinally along its central width by double and triple suture strands. The flat suture and the double and tripled loaded suture strands are folded back on themselves at the distal end of the disposable inserter. The disposable inserter has a stainless steel shaft supporting the forked shaped tip, and a polycarbonate handle. The disposable inserter device is removed at the end of the repair leaving behind an all suture construct. The finished device is provided sterile, for single use.

The Y-Knot® RC All-Suture Anchor w/Two and Three #2 Hi-Fi® Sutures features both surgical techniques for self-punching and pre-drill pilot hole insertion.

A breakdown of catalog numbers, description and suture configuration is included in Table 1.

Table1: Y-Knot® RC All-Suture Anchors

Catalog Number	Description	Suture Configuration
YRC02	Y-Knot® RC All-Suture Anchor w/two #2 Hi-Fi®	1 Blue and 1 White/Black
YRC03	Y-Knot® RC All-Suture Anchor w/three #2 Hi-Fi®	1 Blue, 1 White/Black and 1 White/Blue
YRC02A	Y-Knot® RC All-Suture Anchor w/two #2 Hi-Fi®	1 White/Black and 1 White/Blue
YRC03A	Y-Knot® RC All-Suture Anchor w/three #2 Hi-Fi®	1 White/Black, 1 White/Blue and 1 White

The Y-Knot® RC All-Suture Anchors are inserted using the following instrumentation.

Table 2: Description of Instrumentation

Catalog Number	Description
Y28D	Y-Knot® RC Disposable Drill Bit, 2.8mm
Y-DBP28	Y-Knot® RC Disposable Broaching Punch, 2.8mm
Y-BP28	Y-Knot® RC Broaching Punch, 2.8mm
Y-DGRC	Y-Knot® RC Drill Guide
Y-OBRC	Y-Knot® RC Drill Guide Obturator

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F. Testing

The verification and validation testing of the Y-Knot® RC All-Suture Anchor w/two and three #2 Hi-Fi® Sutures includes fixation strength / pull-out, cyclic loading, insertion, biocompatibility, sterilization, shelf-life and packaging/transportation testing.

G. Intended Use / Indications

The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures. The Y-Knot All-Suture Anchors may be used in either arthroscopic or open surgical procedures. After the suture strands are anchored to the bone, they may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. In conjunction with appropriate postoperative immobilization throughout the healing period, the suture anchor systems stabilize the damaged soft tissue.

H. Substantial Equivalence

The Y-Knot® RC All-Suture Anchor w/Two and Three #2 Hi-Fi® are substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the predicate ConMed Linvatec Y-Knot® Flex All-Suture Anchor, w/two #2 (5 Metric) HI-FI® Suture, 1.8mm and raises 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

January 3, 2014

ConMed Corporation
Ms. Nyrobia Freeman
Regulatory Affairs Specialist
11311 Concept Boulevard
Largo, Florida 33773

Re: K133224
Trade/Device Name: Y-Knot® RC All-Suture Anchor w/Two and Three #2 Hi-Fi® Sutures
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: December 20, 2013
Received: December 23, 2013

Dear Ms. Freeman:

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" (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/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,

Ronald P. Jean -S 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): K133224

Device Name: **Y-Knot® RC All-Suture Anchor w/Two and Three #2 Hi-Fi® Sutures**

INTENDED USE
The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures.

INDICATIONS FOR USE
The Y-Knot All-Suture Anchors may be used in either arthroscopic or open surgical procedures. After the suture strands are anchored to the bone, they may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. In conjunction with appropriate postoperative immobilization throughout the healing period, the suture anchor systems stabilize the damaged soft tissue.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices