January 22, 2020

ConMed Corporation
Carrie Engleman
Lead Regulatory Affairs Specialist
525 French Road
Utica, New York 13502

Re: K193606
Trade/Device Name: Y-Knot® OneStep™ Anchor
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, 2019
Received: December 23, 2019

Dear Ms. Engleman:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laura C. Rose, Ph.D.
Acting Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193606

Device Name

Y-Knot® OneStep™ Anchor

Indications for Use *(Describe)*

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

The devices may be used in either arthroscopic or open surgical procedures. After 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 _____.

I. SUBMITTER

CONMED Corporation
525 French Road
Utica, New York 13502

Phone: 727-399-5574
Fax: 727-399-5264

Contact Person: Carrie Engleman
Date Prepared: December 20, 2019

II. DEVICE NAME

Device Name:	Y-Knot® OneStep™ Anchor
Classification Name:	Fastener, fixation, nondegradable, soft tissue
Regulatory Class:	Class II, per 21 CFR Part 888. 3040
Product Codes:	MBI

III. PREDICATE/ LEGALLY MARKETED DEVICE

Device Name:	Y-Knot® Flex All-Suture Anchor
Company Name:	ConMed Linvatec
510(k) #:	K131035

IV. DEVICE DESCRIPTION

The CONMED Y-Knot® OneStep™ Anchors are manufactured from High Strength Flat Braided Suture and threaded with either one or two #2 (5 metric) Hi-Fi® suture strands or suture ribbon. Y-Knot® OneStep anchors are provided single-use, sterile, and preloaded onto a disposable inserter. The anchors, sutures and disposable inserter are EO Sterilized.

V. INTENDED USE/ INDICATIONS FOR USE

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

The devices may be used in either arthroscopic or open surgical procedures. After 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.

VII. COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table represents a summary of the technological characteristics between the proposed and the predicate device.

	Y-Knot® OneStep™ Anchor Proposed Device	**Y-Knot® Flex All-Suture Anchor, w/ Two #2 (5 metric) Hi-Fi Sutures, 1.8mm Predicate Device**
Device Description	The CONMED Y-Knot® OneStep™ Anchor System are manufactured from High Strength Flat Braided Suture and threaded with either one or two #2 (5 metric) Hi-Fi® suture strands or suture ribbon. Y-Knot OneStep anchors are provided single-use, sterile, and preloaded onto a disposable inserter. The anchors, sutures and disposable inserter are EO Sterilized.	ConMed Linvatec Y-Knot® Flex All-Suture Anchor is manufactured from High Strength Flat Braided Suture and threaded with either one or two #2 (5 metric) Hi-Fi® suture strands. Y-Knot anchors are provided single-use, sterile, and preloaded on a disposable inserter. The anchor, suture and disposable inserter are EO Sterilized.
Intended Use	The non-absorbable implant is intended to reattach soft tissue to bone in orthopedic surgical procedures.	The non-absorbable suture anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures.
Indication for Use	The devices may be used in either arthroscopic or open surgical procedures. After 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	The devices may be used in either arthroscopic or open surgical procedures. After suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the

	thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.	bone. The suture anchor systems thereby stabilize the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.
Contraindications	1. Pathological conditions of bone which would adversely affect Y-Knot anchors. 2. Pathological conditions in the soft tissue to be repaired or reconstructed which would adversely affect suture fixation. 3. Physical conditions that would eliminate, or tend to eliminate, adequate implant support or retard healing. 4. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period. 5. Attachment of artificial ligaments or other implants. 6. Foreign body sensitivity, known or suspected allergies to implant and/or instrument materials. 7. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine. 8. Patients with active sepsis or infection.	Same
Components	All-Suture Anchor Disposable Inserter Suture	All-Suture Anchor Disposable Inserter Suture

Technological Characteristics	Flat-braid suture anchor One or two #2 sutures or ribbon Pilot hole drilled with inserter Press-fit insertion Expandable design Flexible Inserter	Flat-braid suture anchor Two #2 sutures Pilot hole drilled with disposable drill bit Press-fit insertion Expandable design Flexible Inserter
Single Use/ Reusable	Single-Use	Same
Sterilization	EtO Sterility Assurance Level (SAL) of 10^{-6}	Same
Biocompatibility	Materials are Biocompatible and met the requirements of an acceptable biological evaluation per ISO 10993-1 and FDA Guidance	Same
Shelf Life	18-months	5-years

PERFORMANCE DATA

Testing has been completed to demonstrate that the Y-Knot® OneStep™ Anchor performs as intended and is substantially equivalent to the predicate device. Bacterial endotoxin testing was conducted and met the endotoxin limits.

Completed testing includes the following:

Verification Testing

- Reliability
- Fixation/Pull Out
- Displacement
- Cyclic
- Sterilization
- Pyrogen
- Biocompatibility
- Shelf-life
- Transportation
- Post Aging Functional Testing
- MR Safety Testing

Validation Testing

- User Validation
- Packaging And Labeling

VIII. CONCLUSION

Y-Knot® OneStep™ Anchor is substantially equivalent in design, materials, intended use, principles of operation, and technical characteristics to the predicate Y-Knot® Flex All-Suture Anchor. Based upon the findings of our performance testing, the differences present no new issues of safety and efficacy, and the Y-Knot® OneStep™ Anchor is substantially equivalent to the Y-Knot® Flex All-Suture Anchor (K131035).