January 4, 2019

ConMed Corporation
Diana Nader-Martone
Regulatory Affairs Specialist
525 French Road
Utica, New York 13502

Re: K182621
Trade/Device Name: CrossFT™ Knotless Deep Thread Suture Anchor with Disposable Driver
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 30, 2018
Received: December 6, 2018

Dear Ms. Nader-Martone:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K182621

Device Name
CrossFT™ Knotless Deep Thread Suture Anchor with Disposable Driver

Indications for Use *(Describe)*

Intended Use

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

Indications for Use

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 systems thereby stabilize 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 K182621.

I. SUBMITTER

CONMED Corporation
11311 Concept Blvd
Largo, Florida 33773

Phone: 727-399-5425
Fax: 727-399-5264

Contact Person: Diana L. Nader-Martone
Date Prepared: September 21, 2018

II. DEVICE NAME

Device Name:	CrossFT™ Knotless Deep Thread Suture Anchor with Disposable Driver
Common Name:	Nonabsorbable Suture Anchor System
Classification Name:	Fastener, fixation, nondegradable, soft tissue
Regulatory Class:	Class II, per 21 CFR Part 888. 3040
Product Codes:	MBI

III. PREDICATE/ LEGALLY MARKET DEVICE

Device Name:	CrossFT™ Knotless Suture Anchor with Disposable Driver
Company Name:	ConMed
510(k) #:	K163258

IV. REFERENCE/ LEGALLY MARKET DEVICE

Device Name:	ConMed Linvatec Soft Tissue to Bone System
Company Name:	ConMed Linvatec
510(k) #:	K091549

V. DEVICE DESCRIPTION

The CONMED CrossFT™ Knotless Deep Thread Suture Anchors are manufactured from stable PolyEtherEtherKetone (PEEK). The CrossFT Knotless Deep Thread Anchors are a threaded screw-in suture anchor design. The CrossFT™ Knotless Deep Thread Suture Anchors are provided sterile, preloaded on a single-use driver and some include a preloaded sliding #2 (5 metric) Hi-Fi® Suture. The device is EO sterilized.

VI. INTENDED USE/ INDICATIONS FOR USE

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.

VI. 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.

	CrossFT™ Knotless Deep Thread Suture Anchor with Disposable Driver Proposed Device	CrossFT™ Knotless Suture Anchor with Disposable Driver Predicate Device	ConMed Linvatec Soft Tissue to Bone System (CrossFT™ Suture Anchor with Disposable Driver) Reference
Device Description	The CONMED CrossFT™ Knotless Deep Thread Suture Anchors are manufactured from stable PolyEtherEtherKetone (PEEK). The CrossFT Knotless Deep Thread Anchors are a threaded screw-in suture anchor design. The CrossFT™ Knotless Deep Thread Suture Anchors are provided sterile, preloaded on a single-use driver and some include a preloaded sliding #2 (5 metric) Hi-Fi® Suture. The device is EO sterilized.	The CONMED CrossFT™ Knotless Deep Thread Suture Anchors are manufactured from stable PolyEtherEtherKetone (PEEK). The CrossFT Knotless Deep Thread Anchors are a threaded screw-in suture anchor design. The CrossFT™ Knotless Deep Thread Suture Anchors are provided sterile, preloaded on a single-use driver and some include a preloaded sliding #2 (5 metric) Hi-Fi® Suture. The device is EO sterilized.	
Intended Use	The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures.	Same	Same
Indication for Use	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.	Same	Same

	CrossFT™ Knotless Deep Thread Suture Anchor with Disposable Driver Proposed Device	CrossFT™ Knotless Suture Anchor with Disposable Driver Predicate Device	ConMed Linvatec Soft Tissue to Bone System (CrossFT™ Suture Anchor with Disposable Driver) Reference
Contraindications	1. Pathological conditions of bone which would adversely affect the CrossFT™ Knotless Deep Thread Suture Anchor. 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	Same
Components	Non-absorbable Anchor Disposable Driver Threader Suture (some catalog numbers)	Non-absorbable Anchor Disposable Driver Threader Suture (some catalog numbers) Suture Tape (some catalog numbers)	Non-absorbable Anchor Disposable Driver Suture
Technological Characteristics	Non-absorbable, PolyEtherEtherKetone (PEEK) Anchor Screw-in, Knotless Anchor Design Threader Disposable Driver	Same	Non-absorbable, PolyEtherEtherKetone (PEEK) Anchor Screw-in Anchor Design Disposable Driver

PERFORMANCE DATA

Testing has been completed to demonstrate that the CrossFT™ Knotless Deep Thread Suture 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
- Ultimate Fixation Strength
- Cyclic
- Sterilization
- Pyrogen
- Biocompatibility
- Shelf-life
- Post Aging Functional Testing
- MR Safety Testing

Validation Testing

- User Validation
- Packaging
- Transportation

VIII. CONCLUSION

The CrossFT™ Knotless Deep Thread Suture Anchor with Disposable Driver is either substantially equivalent or identical in design, materials, intended use, principles of operation, and technical characteristics to the predicate ConMed CrossFT™ Knotless Suture Anchor with Disposable Driver. Based upon the findings of our performance testing, the differences present no new issues of safety and efficacy, and the CrossFT™ Knotless Deep Thread Suture Anchor with Disposable Driver is substantially equivalent to the ConMed CrossFT™ Knotless Suture Anchor with Disposable Driver (K163258).