



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

ConMed Corporation
Ms. Nyrobia Freeman
Regulatory Affairs Specialist
525 French Road
Utica, New York 13502

January 25, 2017

Re: K163258

Trade/Device Name: CrossFT™ Knotless 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: December 29, 2016
Received: January 5, 2017

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K163258

Device Name
CrossFT™ Knotless Suture Anchor with Disposable Driver

Indications for Use (Describe)

The CrossFT™ Knotless Anchor with Disposable Driver 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.

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.

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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 K163258.

I. SUBMITTER

CONMED Corporation
11311 Concept Blvd
Largo, Florida 33773

Phone: 727-399-5416
Fax: 727-399-5264

Contact Person: Nyrobia Freeman
Date Prepared: November 18, 2016

II. DEVICE NAME

Device Name: CrossFT™ Knotless Suture Anchor with Disposable Driver
Common Name: Nonabsorbable Suture Anchor
Classification Name: Fastener, Fixation, Non-degradable, Soft-Tissue
Regulatory Class: Class II, per 21 CFR Part 888. 3040
Product Codes: MBI

III. PREDICATE/ LEGALLY MARKET DEVICE

Device Name: CrossFT™ Suture Anchor with Disposable Driver
Company Name: CONMED Linvatec
510(k) #: K091549

IV. DEVICE DESCRIPTION

The CrossFT™ Knotless Suture Anchors with Disposable Driver are sterile, single use devices. The CrossFT™ Knotless Suture Anchors are manufactured from PolyEtherEtherKetone (PEEK™). The anchors are provided sterile, single use and preloaded on a disposable driver. The anchors are available in three sizes and nine configurations. (See table 1)

Table 1: CrossFT™ Knotless Suture Anchors with Disposable Driver sizes and configurations

Catalog Number	Description
CFK-40	CrossFT™ Knotless 4.0 mm Suture Anchor
CFK-40TA	CrossFT™ Knotless 4.0 mm Suture Anchor with one 2 mm Hi-Fi® Tape (Blue)



CFK-40TB	CrossFT™ Knotless 4.0 mm Suture Anchor with one 2 mm Hi-Fi® Tape (White/Black)
CFK-475S	CrossFT™ Knotless 4.75 mm Suture Anchor
CFK-475STA	CrossFT™ Knotless 4.75 mm Suture Anchor with one 2 mm Hi-Fi Tape (Blue)
CFK-475STB	CrossFT™ Knotless 4.75 mm Suture Anchor with one 2 mm Hi-Fi Tape (White/Black)
CFK-55S	CrossFT™ Knotless 5.5 mm Suture Anchor
CFK-55STA	CrossFT™ Knotless 5.5 mm Suture Anchor with one 2 mm Hi-Fi® Tape (Blue)
CFK-55STB	CrossFT™ Knotless 5.5 mm Suture Anchor with one 2 mm Hi-Fi® Tape (White/Black)

V. INTENDED USE/ INDICATIONS FOR USE

The CrossFT™ Knotless Suture Anchor with Disposable Driver 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 CrossFT™ Knotless Suture Anchor with Disposable Driver is substantially equivalent in design, materials, intended use, principles of operation, and technical characteristics to the predicate CrossFT™ Suture Anchors with Disposable Driver and raises no new issues of safety or effectiveness.

The similarities and difference between the predicate and proposed Nonabsorbable Suture Anchors are the following-

	CrossFT™ Knotless Suture Anchor with Disposable Driver Proposed	ConMed Linvatec Soft Tissue to Bone System (CrossFT™ Suture Anchor with Disposable Driver) Predicate
Manufacturer	CONMED Corporation	ConMed Linvatec
510k	Pending	K091549
Product Code	MBI	MBI
Classification	II	II
Intended Use	The CrossFT™ Knotless Suture Anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures.	The CrossFT™ Suture Anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures.
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	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

	CrossFT™ Knotless Suture Anchor with Disposable Driver Proposed	ConMed Linvatec Soft Tissue to Bone System (CrossFT™ Suture Anchor with Disposable Driver) Predicate
	thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.	thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.
Contraindications	<ul style="list-style-type: none"> *Pathological conditions of bone which would adversely affect the CrossFT Knotless Suture Anchor. *Pathological conditions in soft tissue to be repaired or reconstructed which would adversely affect suture fixation. *Physical conditions that would eliminate, or tend to eliminate adequate implant support or retard healing. *Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period. *Attachment of artificial ligaments or other implants. *Foreign body sensitivity, known or suspected allergies to implant and/or instrument materials. *This device is not cleared for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine. 	<ul style="list-style-type: none"> *Pathological conditions of bone which would adversely affect the CrossFT Knotless Suture Anchor. *Pathological conditions in soft tissue to be repaired or reconstructed which would adversely affect suture fixation. *Physical conditions that would eliminate, or tend to eliminate adequate implant support or retard healing. *Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period. *Attachment of artificial ligaments or other implants. *Foreign body sensitivity, known or suspected allergies to implant and/or instrument materials. *This device is not cleared for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
Handle	Two pieces that consist of a handle and grip	One piece handle
Anchor Dimensions	4.0 mm, 4.75 mm and 5.5 mm in width 14.5" inches in length	4.5mm, 5.5mm and 6.5mm in width 9.5" inches in length
Suture and/or Suture Tapes configurations	CrossFT™ Knotless 4.0 mm Suture Anchor	Cross FT Anchor with two #2 Hi-Fi Suture, 4.5mm
	CrossFT™ Knotless 4.0 mm Suture Anchor with one 2 mm Hi-Fi Tape (White/Black)	
	CrossFT™ Knotless 4.75 mm Suture Anchor	Cross FT Anchor with three #2 Hi-Fi Suture, 4.5mm
	CrossFT™ Knotless 4.75 mm Suture Anchor with one 2 mm Hi-Fi Tape (Blue)	Cross FT Anchor with two # 2 Hi-Fi Suture, 5.5mm
	CrossFT™ Knotless 4.75 mm Suture Anchor with one 2 mm Hi-Fi Tape (White/Black)	Cross FT Anchor with three # 2 Hi-Fi Suture, 5.5mm
	CrossFT™ Knotless 5.5 mm Suture Anchor	Cross FT Anchor with two # 2 Hi-Fi Suture, 6.5mm
	CrossFT™ Knotless 5.5 mm Suture Anchor with one 2 mm Hi-Fi Tape (Blue)	Cross FT Anchor with two # 2 Hi-Fi Suture, 6.5mm
Threader	Used to thread Hi-Fi® Tape limbs or Hi-Fi® #2 suture limbs through the anchor and driver	None
	<p>For the 4.0 mm anchor, a maximum of two (2) Hi-Fi® Tape limbs can be loaded.</p> <p>For the 4.75 mm and 5.5 mm anchors, a maximum of two (2) Hi-Fi® Tape limbs plus two (2) Hi-Fi® #2 suture limbs, or six (6) Hi-Fi® #2 suture limbs can be loaded.</p>	
Cleat	Available with two (2) suture cleats. The first cleat is part of the handle design and located on top of the handle. This cleat is used to wrap the preloaded suture and/or suture type stands around for packaging purposes. The second	The suture cleat is used to hold the suture strands while tensioning the anchor and for packaging purpose



	CrossFT™ Knotless Suture Anchor with Disposable Driver Proposed	ConMed Linvatec Soft Tissue to Bone System (CrossFT™ Suture Anchor with Disposable Driver) Predicate
	cleat is grey in color and has slotted indents on each side to wrap the suture strands around. The second cleat is also used to maintain tension on the suture strands while the anchor is driven into the bone.	
Packaging	Pouch Tray	Pouch PETG retaining clip Tyvek and Nylon/PE Film pouch
Single Use/ Reusable	Sterile, Single-Use	Sterile, Single-Use
Sterilization	Eto	Eto
Components	Bone Punch Bone Tap Drill Bit	Bone Punch Bone Tap
Shelf-Life	18 months	5 year

PERFORMANCE DATA

Testing has been completed to demonstrate that the CrossFT™ Knotless Suture Anchor with Disposable Driver performs as intended and is substantially equivalent to the predicate device. The bacterial endotoxin testing was conducted and met the endotoxin limits.

Completed testing includes the following:

- Reliability
- Packaging
- Ultimate Fixation Strength
- Cyclic
- Sterilization
- Pyrogenicity
- Verification Testing
- Transportation
- Biocompatibility
- User Validation
- Shelf-life

VIII. CONCLUSION

The CrossFT™ Knotless 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 CrossFT™ 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 Suture Anchor with Disposable Driver is substantially equivalent to the CrossFT™ Suture Anchor with Disposable Driver (K091549).