DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 29, 2017

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

Re: K171592
Trade/Device Name: CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: May 30, 2017
Received: May 31, 2017

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. 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 (DICE) 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 (DICE) 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

# Indications for Use

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

510(k) Number *(if known)*

K171592

Device Name
CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver

Indications for Use *(Describe)*
The CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver is intended to reattach soft tissue to bone in the following orthopedic surgical procedures:

| Procedure | Joint |
|---|---|
| Rotator Cuff Repair | Shoulder |
| Achilles Repair | Ankle |
| Bicep Tenodesis | Shoulder |
| Gluteus Medius Repair | Hip |
| Medial Patellofemoral Ligament (MPFL) | Knee |

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.**

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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 K171592.

## I. SUBMITTER

CONMED Corporation
525 French Road
Utica, New York 13502

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

Contact Person: Diana L. Nader-Martone
Date Prepared: May 30, 2017

## II. DEVICE NAME

| | |
|---|---|
| Device Name: | CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver |
| Common Name: | Bioabsorbable Suture Anchor |
| Classification Name: | Fastener, fixation, biodegradable, soft tissue |
| Regulatory Class: | Class II, per 21 CFR Part 888. 3030 |
| Product Codes: | MAI |

## III. PREDICATE DEVICE

| | |
|---|---|
| Device Name: | CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver |
| Company Name: | ConMed Corporation |
| 510(k) #: | K170501 |

## IV. DEVICE DESCRIPTION

The CrossFT™ Knotless Biocomposite Suture Anchors with Disposable Driver are sterile, single use devices. The CrossFT™ Knotless Biocomposite Suture Anchors with Disposable Driver are manufactured from polylactide copolymer (96L/4D PLA) and β-Tricalcium Phosphate (β-TCP). The anchors are provided sterile, single use and preloaded on a disposable driver. The anchors are available in three sizes and nine configurations.

## V. INTENDED USE/ INDICATIONS FOR USE

The CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver is intended to reattach soft tissue to bone in the following orthopedic surgical procedures:

| Procedure | Joint |
|---|---|
| Rotator cuff repair | Shoulder |
| Achilles Repair | Ankle |
| Bicep Tenodesis | Shoulder |
| Gluteus Medius Repair | Hip |
| Medial Patellofemoral Ligament (MPFL) | Knee |

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 Biocomposite Suture Anchor with Disposable Driver Proposed | CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver Predicate |
|---|---|---|
| Device Description | Same | The CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Drivers are sterile, single use devices. The CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Drivers are manufactured from polylactide copolymer (96L/4D PLA) and β-Tricalcium Phosphate (β-TCP). The anchors are provided sterile, single use and preloaded on a disposable driver. The anchors are available in three sizes and nine configurations. |
| Intended Use | The CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver is intended to reattach soft tissue to bone in the following orthopedic surgical procedures:<br>**Procedure** — **Joint**<br>Rotator Cuff Repair — Shoulder<br>Achilles Repair — Ankle<br>Bicep Tenodesis — Shoulder<br>Gluteus Medius Repair — Hip<br>Medial Patellofemoral Ligament (MPFL) — Knee | The CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver is intended to reattach soft tissue to bone in orthopedic surgical procedures. |
| Indication for Use | Same | 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. |

| | CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver Proposed | CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver Predicate |
|---|---|---|
| Contraindications | Same | *Pathological conditions of bone which would adversely affect the CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver with Disposable Driver.<br>* Pathological conditions in the soft tissue to be repaired or reconstructed which would adversely affect suture fixation.<br>* Physical conditions that would eliminate, or tend to eliminate, adequate implant support or retard healing.<br>* Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.<br>* Attachment of artificial ligaments or other implants.<br>* Foreign body sensitivity, known or suspected allergies to implant and/ or instrument materials.<br>* This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine. |
| Components | Same | Bioabsorbable anchor<br>Disposable Driver<br>Suture and/or Suture Tape<br>Threader |

## VII. PERFORMANCE DATA

Testing has been completed to demonstrate that the CrossFT™ Knotless Biocomposite 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. The test parameters utilized were supported by clinical data in the literature to support the specific indications and corresponding anatomic locations in this submission.

Completed testing includes the following:

Verification Testing

- Reliability
- Ultimate Fixation Strength
- Cyclic
- Sterilization
- Pyrogenicity
- Biocompatibility
- Shelf-life

Validation Testing

- User Validation
- Packaging
- Transportation

## VIII. CONCLUSION

The CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver is identical in design, materials, principles of operation, and technical characteristics to the predicate, and substantially equivalent in intended use to the predicate. Based upon the findings of our performance testing, the difference regarding intended use presents no new issues of

safety and efficacy, and the proposed, CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver is substantially equivalent to the CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver (K170501).