July 19, 2018

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

Re: K180763
Trade/Device Name: CuffLink Implant System Biocomposite
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: June 15, 2018
Received: June 18, 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. 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.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180763

Device Name
CuffLink Implant System Biocomposite

Indications for Use *(Describe)*

INTENDED USE
The Implant System 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.

INDICATIONS FOR USE
The CuffLink™ Implant System Biocomposite is indicated to reattach soft tissue to bone in the following orthopedic surgical procedures.

Procedure	Joint
Rotator cuff repair	Shoulder
Achilles Repair	Ankle

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

I. SUBMITTER

CONMED Corporation
525 French Road
Utica, NY 13502

Phone: 727.399.5425
Fax: 727.399.5264

Contact Person: Diana L. Nader-Martone
Date Prepared: June 15, 2018

II. DEVICE

Device Name:	**CuffLink™ Implant System Biocomposite**
Trade Name/Common Name:	Bioabsorbable Suture Anchor
Classification Name:	Fastener, fixation, biodegradable, soft tissue
Regulatory Class:	Class II, per 21 CFR Part 888.3030
Product Code:	MAI, MBI

III. PREDICATE DEVICE

Device Name:	CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver
Manufacturer:	CONMED Corporation
510(k) Number:	K171592

IV. REFERENCE DEVICE

Device Name:	CuffLink™ Implant System
Manufacturer:	CONMED Corporation
510(k) Number:	K171725

V. DEVICE DESCRIPTION

The CuffLink™ Implant System Biocomposite consists of six kits that are provided sterile, for single-use only. Each kit contains four (4) suture anchors in various combinations of the CrossFT Knotless Biocomposite Suture Anchor with Disposable Driver (K171592) and Y-Knot RC All-Suture Anchor (K133224). Two (2) of the anchors are meant to be used as the primary/medial row and two (2) anchors are meant to be used for the knotless/lateral row. Each kit also contains one (1) disposable broaching punch, and one (1) suture passing loop assembled in a single PETG tray, and sealed in a Tyvek pouch.

VI. INTENDED USE/INDICATIONS FOR USE STATEMENT

INTENDED USE

The Implant System 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.

INDICATIONS FOR USE

The CuffLink™ Implant System Biocomposite is indicated to reattach soft tissue to bone in the following orthopedic surgical procedures.

Procedure	Joint
Rotator Cuff Repair	Shoulder
Achilles Repair	Ankle

VII. COMPARISION OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

CONMED's CuffLink Implant System Biocomposite is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the CONMED CrossFT Knotless Biocomposite Suture Anchor (predicate device (K171592)) with Disposable Driver and CuffLink™ Implant System (reference device (K171725)) and raises no new issues of safety or effectiveness.

The similarities and differences between the proposed, predicate, and reference devices are summarized in the table below.

	Proposed Device	**Predicate Device**	**Reference Device**
Device	CuffLink™ Implant System Biocomposite	CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver	CuffLink™ Implant System
510(k) Number		K171592	K171725
Manufacturer	CONMED Corporation		
Intended Use	The Implant System 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,	The biocomposite suture anchor is intended to reattach soft tissue to bone in the following orthopedic surgical procedures: Procedure — Joint Rotator cuff repair — Shoulder Achilles Repair — Ankle Biceps Tenodesis — Shoulder Gluteus Medius Repair — Hip Medial Patellofemoral Ligament (MPFL) — Knee	The CuffLink™ Implant System is intended to reattach soft tissue to bone in orthopedic surgical procedures.

	throughout the healing period.		
Indications for Use	The CuffLink™ Implant System Biocomposite is indicated to reattach soft tissue to bone in the following orthopedic surgical procedures. Procedure — Joint Rotator Cuff Repair — Shoulder Achilles Repair — Ankle	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.	The Implant System 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.
	Proposed Device	**Predicate Device**	**Reference Device**
Device	CuffLink™ Implant System Biocomposite	CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver	CuffLink™ Implant System
Contraindications	1. Pathological conditions of bone which would adversely affect the CuffLink™ Implant System Biocomposite. 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	1. Pathological conditions of bone which would adversely affect the CrossFT™ Knotless Biocomposite 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	1. Pathological conditions of bone which would adversely affect the CuffLink™ Implant System. 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

	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.	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.	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.
	Proposed Device	**Predicate Device**	**Reference Device**
Device	CuffLink™ Implant System Biocomposite	CrossFT™ Knotless Biocomposite Suture Anchor with Disposable Driver	CuffLink™ Implant System
Reuse/Sterilization	Single-Use		
Principle of Operation	Soft tissue to bone fixation		
Biocompatibility	In accordance with ISO 10993-1 and FDA # G95-1		
Packaging	Multiple implants in tray	Single device unit in package	Multiple implants in tray
Materials	UHMWPE, polyester, nylon suture, stainless steel, polycarbonate, 96L/4D co-polymer and ß-TCP		UHMWPE, polyester, nylon suture, stainless steel, polycarbonate, PEEK Optima®

VIII. PERFORMANCE DATA

Testing has been completed to demonstrate that the Cufflink™ Implant System Biocomposite 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 biocompatibility, packaging, user validation, shelf life, sterilization, transportation, and pyrogenicity.

IX. CONCLUSION

CONMED's Cufflink™ Implant System Biocomposite is either substantially equivalent or identical in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the predicate and reference devices. Based upon the findings of performance testing, the differences do not present any novel issues of safety and efficacy, and is substantially equivalent to the predicate device.