June 28, 2019

CONMED Corporation
Diana Nader-Martone
Senior Regulatory Affairs Specialist
11311 Concept Boulevard
Largo, Florida 33773

Re: K190582
Trade/Device Name: MicroLink™ All-Suture Button Fixation System (Radiopaque)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN
Dated: May 28, 2019
Received: May 29, 2019

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/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,

Laurence D. Coyne, Ph.D.
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)*

K190582

Device Name

MicroLink™ All-Suture Button Fixation System (Radiopaque)

Indications for Use *(Describe)*

Intended Use

The MicroLink™ All-Suture Button Fixation System, when used for fixation of bone-to-bone or soft-tissue-to-bone, is intended as a fixation post, distribution bridge, or for distributing suture tension over areas of ligament or tendon repair.

Indications for Use

The CONMED MicroLink All-Suture Button Fixation System is indicated for fixation of bone-to-bone as an adjunct in the following orthopedic surgical procedures:

Procedure	Anatomic Location
Carpometacarpal Suspension	Hand

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 K190582.

I. SUBMITTER

CONMED Corporation
11311 Concept Blvd
Largo, Florida 33773

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

Contact Persons: Diana L. Nader-Martone or Kathy Reddig
Date Prepared: April 25, 2019

II. DEVICE NAME

Device Name:	MicroLink™ All-Suture Button Fixation System (Radiopaque)
Common Name:	Nonabsorbable Suture Fixation System
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class:	Class II, per 21 CFR Part 888. 3030
Product Codes:	HTN

III. PREDICATE/ LEGALLY MARKET DEVICE

Device Name:	CMC Mini TightRope
Company Name:	Arthrex, Inc.
510(k) #:	K140328

IV. DEVICE DESCRIPTION

The MicroLink™ All-Suture Button Fixation System (Radiopaque) is an all-suture suspension device with one strand of #2 (5 metric) Hi-Fi® suture, a radiopaque flat braid Hi-Fi® Suture Button and a radiopaque flat braid Hi-Fi® suture Backstop threaded on a Loader. A suture passing drill is provided with a nitinol loop for passing. A trapezium pin is provided to facilitate manipulation of the trapezium during trapeziectomy. All four catalog numbers are provided sterile, intended for single-use.

V. INTENDED USE/ INDICATIONS FOR USE

The MicroLink™ All-Suture Button Fixation System, when used for fixation of bone-to-bone or soft-tissue-to-bone, is intended as a fixation post, distribution bridge, or for distributing suture tension over areas of ligament or tendon repair.

The CONMED MicroLink All-Suture Button Fixation System is indicated for fixation of bone-to-bone as an adjunct in the following orthopedic surgical procedures:

Procedure	**Anatomic Location**
Carpometacarpal Suspension	Hand

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.

	MicroLink™ All-Suture Button Fixation System (Radiopaque) Proposed Device	CMC Mini TightRope Predicate Device
Device Description	The MicroLink™ All-Suture Button Fixation System (Radiopaque is an all-suture suspension device with one strand of #2 (5 metric) Hi-Fi® suture, a radio flat braid Hi-Fi® Suture Button and a radiolucent flat braid Hi-Fi® suture Backstop threaded on a Loader. A suture passing drill is provided with a nitinol loop for passing. A trapezium pin is provided to facilitate manipulation of the trapezium during trapeziectomy. All four catalog numbers are provided sterile, intended for single-use.	
Intended Use	The MicroLink™ All-Suture Button Fixation System, when used for fixation of bone-to-bone or soft-tissue-to-bone, is intended as a fixation post, distribution bridge, or for distributing suture tension over areas of ligament or tendon repair.	Same
Indication for Use	The CONMED MicroLink All-Suture Button Fixation System is indicated for fixation of bone-to-bone as an adjunct in the following orthopedic surgical procedures: **Procedure** — **Anatomic Location** Carpometacarpal Suspension — Hand	Specifically, the Arthrex CMC Mini TightRope is indicated for Carpal Metacarpal (CMC) joint arthroplasty as an adjunct in the suspension of the thumb metacarpal during the healing process of hematoma distraction arthroplasty by providing stabilization at the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.
Contraindications	1. Pathological conditions of bone which would adversely affect the device. 2. Physical conditions that would eliminate, or tend to eliminate, adequate implant support or retard healing. 3. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.	1. Insufficient quantity or quality of bone. 2. Blood supply limitations and previous infections, which may retard healing. 3. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation. 4. Foreign Body Reactions. See Adverse Effects-Allergic Type Reactions. 5. Any active infection or blood supply limitations.

	MicroLink™ All-Suture Button Fixation System (Radiopaque) Proposed Device	CMC Mini TightRope Predicate Device
	4. Attachment of artificial ligaments or other implants. 5. Foreign body sensitivity, known or suspected allergies to implant and/ or instrument materials. 6. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, 7. thoracic or lumbar spine. 8. Patients with active sepsis or infection.	6. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period. 7. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb, or disrupt the growth plate. 8. Do not use for surgeries other than those indicated.
Components	All-Suture Button (Radiopaque) with suture All-Suture Backstop Loader Trapezium Pin Suture Passing Drill	TightRope Suture Construct with suture Oblong Button for Mini TightRope Loader Trapeziectomy Tool w/ Handle Suture Passing K-wire, short Suture Passing K-wire, long Suture Passing Wire, 8 inches
Technological Characteristics	Flat-braid suture button Flat-braid suture backstop One #2 suture Radiopaque implant Suture Passing Drill to pull suture through one or more bones Instrument to maneuver and remove bone	Stainless steel button Stainless steel backstop One #2 suture Radiopaque implant Suture passing drill to pull suture through one or more bones Instrument to maneuver and remove bone

VIII. PERFORMANCE DATA

Testing has been completed to demonstrate that the MicroLink™ All-Suture Button Fixation System (Radiopaque) 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:

<u>Verification Testing</u>
- Sterilization
- Pyrogen
- Biocompatibility
- Shelf-life

<u>Side-by-Side Testing</u>
- Reliability
- Ultimate Fixation Strength
- Cyclic

<u>Validation Testing</u>
- User Validation
- Packaging
- Transportation

IX. CONCLUSION

The MicroLink™ All-Suture Button Fixation System (Radiopaque) is either substantially equivalent or identical in design, materials, intended use, principles of operation, and technical characteristics to the predicate CMC Mini TightRope. Based upon the findings of our performance testing, the differences present no new issues of safety and efficacy, and the MicroLink™ All-Suture Button Fixation System (Radiopaque) is substantially equivalent to the CMC Mini TightRope (K140328).