CONMED Corporation
Ms. Dionne Sanders
Manager, Regulatory Affairs, Orthopedic Division
525 French Road
Utica, New York 13502

Re: K171725
Trade/Device Name: CuffLink Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 9, 2017
Received: June 12, 2017

Dear Ms. Sanders:

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
Indications for Use

The CuffLink Implant System is intended to reattach soft tissue to bone in orthopedic surgical procedures.

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.

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

I. SUBMITTER

CONMED Corporation
525 French Road
Utica, NY  13502

Phone: 727-399-5564
Fax: 727-399-5264

Contact Person:  Dionne Sanders, RAC
Date Prepared:  June 9, 2017

II. DEVICE

Name of Device:  CuffLink Implant System
Trade Name/Common Name:  Non-absorbable Suture Anchors
Classification Name:  Smooth or threaded metallic bone fixation fastener
Regulatory Class:  Class II, per 21 CFR Part 888.3040
Product Code:  MBI

III. PREDICATE DEVICE

Device Name:  CrossFT Knotless Suture Anchor w/Disposable Driver
Manufacturer:  CONMED Corporation
510(k) #:  K163258

IV. DEVICE DESCRIPTION

The CuffLink™ Implant System consists of six kits that will be provided sterile, for single-use only. Each kit will contain four suture anchors, one disposable broaching punch, and one suture passing loop assembled in a single PETG tray, and sealed in a Tyvek pouch. The tray is subsequently placed in a folding carton.

INTENDED USE / INDICATIONS FOR USE

The CuffLink Implant System is intended to reattach soft tissue to bone in orthopedic surgical procedures.

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.

V. COMPARISION OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

CONMED’s CuffLink Implant System is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the CONMED CrossFT Knotless and Y-Knot RC Suture Anchors and raises no new issues of safety or effectiveness.

The similarities and differences between the predicate and proposed sterilization trays are the following:

<table>
<thead>
<tr>
<th>Proposed Device</th>
<th>Predicate Device</th>
<th>Reference Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>CuffLink Implant System</td>
<td>CrossFT Knotless Suture Anchor</td>
<td>Y-Knot RC Suture Anchor</td>
</tr>
<tr>
<td>510k Number</td>
<td>TBD</td>
<td>K163258</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>CONMED Corporation</td>
<td></td>
</tr>
<tr>
<td>Intended Use</td>
<td>Intended to reattach soft tissue to bone in orthopedic surgical procedures.</td>
<td></td>
</tr>
<tr>
<td>Indications for Use</td>
<td>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 the appropriate postoperative immobilization, throughout the healing period.</td>
<td>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 the appropriate postoperative immobilization, throughout the healing period.</td>
</tr>
<tr>
<td>Contraindications</td>
<td>1. Pathological conditions of bone which would adversely affect the CuffLink Implant System. 2. Pathological conditions in the soft tissue to be repaired</td>
<td>1. Pathological conditions of bone which would adversely affect the CrossFT Knotless Suture Anchor. 2. Pathological conditions in the soft tissue to be repaired</td>
</tr>
<tr>
<td>How Supplied</td>
<td>Sterile, Kit (anchor implants, instrumentation, suture)</td>
<td>Sterile anchor with delivery system</td>
</tr>
<tr>
<td>--------------</td>
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<tr>
<td>Reuse/Sterilization</td>
<td>Single-Use</td>
<td></td>
</tr>
<tr>
<td>Shelf-Life</td>
<td>18 month</td>
<td>5-years</td>
</tr>
<tr>
<td>Principle of Operation</td>
<td>For soft tissue to bone fixation</td>
<td></td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>In accordance with ISO 10993-1 and FDA# G95-1</td>
<td></td>
</tr>
<tr>
<td>Packaging</td>
<td>Multiple implants packaged in a tray to</td>
<td>Packaged as a single device</td>
</tr>
</tbody>
</table>
VI. PERFORMANCE DATA

Testing has been completed to demonstrate that the Cufflink Implant System performs as intended and is substantially equivalent to the predicate device. The bacterial endotoxin testing was conducted and met the limits.

Completed test data includes the following:

- Biocompatibility
- Packaging
- User Validation
- Shelf-life
- Sterilization
- Transportation
- Pyrogenicity

VII. CONCLUSION

CONMED’s Cufflink Implant System is either substantially equivalent or identical in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the CrossFT Knotless Suture Anchor w/Disposable Driver. Based upon the findings of our performance testing, the differences present no new issues of safety and efficacy and is substantially equivalent to the predicate device.