January 8, 2019

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

Re: K182439
Trade/Device Name: TruShot™ with Y-Knot® Shallow All-Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 16, 2018
Received: November 19, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Laurence D. Coyne -S

For 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)*
K182439

Device Name
TruShot™ with Y-Knot® Shallow All-Suture Anchor

Indications for Use *(Describe)*
Intended Use
The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures.

Indications 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 systems thereby stabilize 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 K182439.

I. SUBMITTER

CONMED Corporation
11311 Concept Blvd
Largo, Florida 33773

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

Contact Person: Diana L. Nader-Martone
Date Prepared: September 18, 2018

II. DEVICE NAME

Device Name:	TruShot™ with Y-Knot® Shallow All-Suture Anchors
Common Name:	Nonabsorbable Suture Anchor System
Classification Name:	Fastener, fixation, nondegradable, soft tissue
Regulatory Class:	Class II, per 21 CFR Part 888. 3040
Product Codes:	MBI

III. PREDICATE/ LEGALLY MARKETED DEVICE

Device Name:	Mitek Mini QuickAnchor® Plus
Company Name:	Mitek
510(k) #:	K992487

IV. REFERENCE DEVICE

Device Name:	ConMed Linvatec Y-Knot™ All-Suture Anchor
Company Name:	ConMed Linvatec
510(k) #:	K111779

V. ADDITIONAL REFERENCE DEVICE

Device Name:	Y-Knot Flex All-Suture Anchor, w/Two #2 (5 Metric) Hi-Fi Sutures, 1.8mm
Company Name:	ConMed Linvatec
510(k) #:	K131035

VI. DEVICE DESCRIPTION

The CONMED TruShot™ with Y-Knot® Shallow All-Suture Anchor is manufactured from High Strength Flat Braided Suture threaded with either one #0 (3.5 metric) or one #2-0 (3 metric) Hi-Fi® suture strand with needles. Each All-Suture Anchor is preloaded on a disposable inserter, and pre-assembled with a disposable drill bit and guide handle. The anchor, suture(s) with needles, inserter, drill bit, and guide handle are pre-assembled and provided sterile, intended for single-use. The device is EO Sterilized.

VII. INTENDED USE/ INDICATIONS FOR USE

The non-absorbable suture anchors are 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.

VIII. 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.

	TruShot™ with Y-Knot® Shallow All-Suture Anchor Proposed Device	Mitek Mini QuickAnchor® Plus Predicate Device	ConMed Linvatec Y-Knot® All-Suture Anchor 1st Reference Device	Y-Knot Flex All-Suture Anchor, w/Two #2 (5 Metric) Hi-Fi Sutures, 1.8mm 2nd Reference Device
Device Description	The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures.	Mitek Mini QuickAnchor® Plus is a sterile, disposable bone anchor supplied preloaded on an inserter with a polyester suture.	Same as proposed	Same as proposed
Intended Use	The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures.	N/A – Incorporated into their indications statement	Same as proposed	Same as proposed
Indication for Use	The 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	Mitek Mini QuickAnchor® Plus indications: <u>Shoulder</u>: Bankart repair <u>Ankle</u>: Midfoot Reconstructions <u>Foot</u>: Hallux Valgus Reconstruction	Same as proposed	Same as proposed

	TruShot™ with Y-Knot® Shallow All-Suture Anchor Proposed Device	Mitek Mini QuickAnchor® Plus Predicate Device	ConMed Linvatec Y-Knot® All-Suture Anchor 1st Reference Device	Y-Knot Flex All-Suture Anchor, w/Two #2 (5 Metric) Hi-Fi Sutures, 1.8mm 2nd Reference Device
	bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.	Wrist: Scapholunate ligament Reconstruction Hand: Ulnar or Lateral Collateral Ligament Reconstruction Pubis: Fixation in the pubis for bladder neck suspicion to resolve stress urinary incontinence		
Contraindications	1. Reattachment of intracapsular knee ligaments (ACL & PCL). 2. Pathological conditions of bone which would adversely affect the Y-Knot anchor. 3. Pathological conditions in the soft tissue to be repaired or reconstructed which would adversely affect suture fixation. 4. Physical conditions that would eliminate, or tend to eliminate, adequate implant support or retard healing. 5. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period. 6. Attachment of artificial ligaments or other implants. 7. Foreign body sensitivity, known or suspected allergies to implant and/or instrument materials. 8. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.	1. Reattachment of intracapsular knee ligaments (ACL & PCL). 2. Surgical procedures other than those listed in the INDICATIONS section. 3. Pathologic conditions of bone, such as cystic changes or severe osteopenia, which would impair its ability to securely fix the Depuy Mitek Anchor, are contraindicated. 4. Pathological changes in the soft tissues sutured to the bone which would prevent its secure fixation by the suture are contraindicated. 5. Comminuted bone surface, which would militate against secure fixation of the Depuy Mitek Anchor, is contraindicated. 6. Physical conditions that would eliminate or tend to eliminate adequate implant support or retard healing, i.e., blood supply limitation, previous infections, etc. are contraindicated. 7. Conditions which tend to preempt the patient's ability or the healing period, such as senility, mental	1. Pathological conditions of bone which would adversely affect the Y-Knot 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 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. 8. Patients with active sepsis or infection.	1. Pathological conditions of bone which would adversely affect the Y-Knot 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 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. 8. Patients with active sepsis or infection.

	TruShot™ with Y-Knot® Shallow All-Suture Anchor Proposed Device	Mitek Mini QuickAnchor® Plus Predicate Device	ConMed Linvatec Y-Knot® All-Suture Anchor 1st Reference Device	Y-Knot Flex All-Suture Anchor, w/Two #2 (5 Metric) Hi-Fi Sutures, 1.8mm 2nd Reference Device
	9. Patients with active sepsis or infection.	illness or alcoholism are contraindicated. 8. The Depuy Mitek Anchor is not designed for and should never be used to attach artificial ligaments or other implants.		
Components	All-Suture Anchor Disposable Guide Handle Suture	Handle Shaft Anchor Suture Needles	All-Suture Anchor Disposable Driver Suture	All-Suture Anchor Disposable Driver Suture
Technological Characteristics	Soft-body suture anchor One #0 or #2-0 suture Drilled pilot hole Press-fit insertion Expandable design	Hard-body suture anchor One #2/0 suture Drilled pilot hole Press-fit insertion Expandable design	Soft-body suture anchor One #2 suture Drilled pilot hole Press-fit insertion Expandable design	Soft-body suture anchor Two #2 sutures Drilled pilot hole Press-fit insertion Expandable design

IX. PERFORMANCE DATA

Testing has been completed to demonstrate that the TruShot™ with Y-Knot® Shallow All-Suture Anchor performs as intended and is substantially equivalent to the predicate device. Performance testing was addressed by side-by-side testing comparing the subject device to predicate K992487. Bacterial endotoxin testing was conducted and met the endotoxin limits.

Completed testing includes the following:

Verification Testing
- Sterilization
- Pyrogen
- Biocompatibility
- Shelf-life
- Post Aging Functional Testing
- MR Safety Testing

Side-by-Side Testing
- Reliability
- Ultimate Fixation Strength
- Cyclic

Validation Testing
- User Validation
- Packaging
- Transportation

X. CONCLUSION

The TruShot™ with Y-Knot® Shallow All-Suture Anchor is either substantially equivalent or identical in design, materials, intended use, principles of operation, and technical characteristics to the predicate Mitek QuickAnchor Plus device. Based upon the findings

of our performance testing, the differences present no new issues of safety and efficacy, and the TruShot™ with Y-Knot® Shallow All-Suture Anchor is substantially equivalent to the Mini QuickAnchor Plus (K992487) devices.