January 29, 2026

Conmed Corporation
Mirela Gjini
Sr. Specialist Regulatory Affairs
525 French Rd.
Utica, New York 13502

Re: K253763
Trade/Device Name: Y-Knotless™ Flex Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 25, 2025
Received: January 15, 2026

Dear Mirela Gjini:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253763

Please provide the device trade name(s).

Y-Knotless™ Flex Anchors

Please provide your Indications for Use below.

The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures.

The Y-Knotless™ Flex Anchors 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.
The Y-Knotless™ Flex Anchors may be used in the following orthopedic procedures:

1. Shoulder Labrum
2. MPFL Reconstruction
3. Foot and Ankle
4. Biceps
5. Meniscal Root Repair

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

CONMED Corporation
Y-Knotless™ Flex Anchors

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 _K253763_____.

I. SUBMITTER

Manufacturer:
CONMED Corporation
525 French Road
Utica, NY 13502

Official Contact Person:
Mirela Gjini
525 French Road
Utica, NY 13502
(O) 727-509-6143

Date Prepared: January 15, 2026

II. DEVICE NAME

Device Name:	Y-Knotless™ Flex Anchors
Common Name:	Fastener, Fixation, Nondegradable, Soft tissue
Classification Name:	Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class:	Class II, per 21 CFR Part 888.3040
Product Codes:	MBI

III. PREDICATE/ LEGALLY MARKETED DEVICE

Device Name:	Y-Knot® Flex All-Suture Anchor, w/two #2 (5 metric) Hi-Fi Sutures, 1.8mm
Company Name:	Linvatec Corp. d/b/a ConMed Linvatec
510(k) #:	K131035

IV. DEVICE DESCRIPTION

The Y-Knotless™ Flex Anchors are a non-absorbable, all-suture, knotless implant, that are supplied single use, sterilized via ethylene oxide (ETO) to a SAL of 10-6. The implant anchors are composed of a white flat braided ultra-high molecular weight polyethylene (UHMWPE) suture anchor, a tapered #2 Hi-Fi® repair suture either white/black or green/white/black, and a #2-0 Hi-Fi® shuttle suture, blue and black. The implants are pre-loaded on a disposable driver with sutures cleated to the handle. The anchors require a 1.8 mm pre-drilled bone hole created using Class I, exempt instrumentation.

V. INTENDED USE/ INDICATIONS FOR USE

The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures.

The Y-Knotless™ Flex Anchors 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.

The Y-Knotless™ Flex Anchors may be used in the following orthopedic procedures:

1. Shoulder Labrum
2. MPFL Reconstruction
3. Foot and Ankle
4. Biceps
5. Meniscal Root Repair

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.

	Proposed Device	**Predicate Device**
Manufacturer:	CONMED	Linvatec Corp. d/b/a ConMed Linvatec
Device Name	Y-Knotless™ Flex Anchors	Y-Knot® Flex All-Suture Anchor, W/Two #2 (5 Metric) Hi-Fi Sutures, 1.8mm
510k Number	K253763	K131035
Intended Use/Indications for Use	The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures. The Y-Knotless™ Flex Anchors 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.	The device is 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.

	Proposed Device	Predicate Device
	The Y-Knotless™ Flex Anchors may be used in the following orthopedic procedures: 1. Shoulder Labrum 2. MPFL Reconstruction 3. Foot and Ankle 4. Biceps 5. Meniscal Root Repair	
Contraindications	1. Pathological conditions of bone which would adversely affect Y-Knotless™ Flex Anchors. 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. 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, thoracic or lumbar spine. 7. Patients with active sepsis or infection.	1. Pathological conditions of bone which would adversely affect Y-Knot anchors. 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.
How Supplied	Same	Sterile Anchor w/Delivery System (1ea)
Single Use /Reusable	Same	Single-Use Only
Sterilization	Same	Ethylene Oxide (10^{-6})
Shelf-Life	3-Years	5-Years
Principle of Operation	Suture anchors for soft tissue to bone fixation	Suture anchors for soft tissue to bone fixation
Biocompatibility	In accordance with ISO 10993-1	In accordance with ISO 10993-1 and FDA# G95-1

	Proposed Device	Predicate Device
Materials	**Implant/Anchor**: White (natural) UHMWPE flat suture **Implant Suture:** Round Tapered #2 UHMWPE **(**Green/White/Black or White/Black) **Non-Implant Shuttle Suture:** Shuttle, 2-0, Blue and Black UHMWPE **Driver:** Shaft - 304 SS Handle – ABS	**Implant/Anchor:** Natural UHMWPE flat suture **Implant Suture:** Two #2 suture strands, UHMWPE (blue/white, black/white) **Driver:** Shaft - 304 SS Handle - ABS
Packaging	Same	Packaged as a single-unit device
Design	Folded flat suture, push-in, knotless splice loop. Assembled and packed with non-absorbable, ultra-high molecular weight polyethylene suture a tapered #2 (5 metric) Hi-Fi® repair suture, and a #2-0 (3 metric) Hi-Fi® shuttle suture	Folded flat suture, push-in. Assembled and packed with two non-absorbable braided #2 ultra-high molecular weight polyethylene suture
Dimensions:	Same	1.8mm width x 13mm length x .47mm thickness
Compatibility w/ environment	Same	Designed to operate in normal operating room environments.
Where used	Same	Hospitals, clinics, and surgery centers.
MR Compatibility	Same	MR Safe
Instrumentation	Same	Drill Guides Drill Bit Obturators
Performance Testing	Same	Cyclic Loading Insertion Fixation/Pull out

VII. PERFORMANCE DATA

Testing has been completed to demonstrate that Y-Knotless™ Flex Anchors performs as intended and is substantially equivalent to the predicate device. Completed testing includes the following:

Performance Testing (ASTM F3960)
Insertion
Ultimate Pull Displacement Resistance
Cyclic

Validation
User Validation
Packaging (Transportation and Shelf-life)
Packaging and Labeling User Validation
Sterilization
Transportation and Post Transportation

Well-established Method Testing
Pyrogen (Bacterial Endotoxin)
Biocompatibility
Shelf-life
Post Shelf-Life Functional Test

VIII. CONCLUSION

The Y-Knotless™ Flex Anchors are substantially equivalent in design, materials, intended use, principles of operation, and technical characteristics to the predicate Y-Knot® Flex All-Suture Anchor, w/two #2 (5 metric) Hi-Fi Sutures, 1.8mm. Based upon the findings of the performance testing, the differences present no new issues of safety and effectiveness, and the Y-Knotless™ Flex Anchors are substantially equivalent to the predicate device (K131035).