



May 13, 2026

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

Re: K261363

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: April 24, 2026
Received: April 27, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Thomas Mcnamara -S

For: Christopher Ferreira, MS.

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.

K261363

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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 in skeletally mature pediatric and adult patients. The suture anchor systems thereby stabilize the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

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](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☒ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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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 K261363.

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: April 24, 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. PRIMARY PREDICATE/ LEGALLY MARKETED DEVICE

Device Name:	Y-Knotless™ Flex Anchors
Company Name:	CONMED Corporation
510(k) #:	K253763

ADDITIONAL PREDICATE DEVICES/ LEGALLY MARKETED DEVICE

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

Device Name:	Knotilus+ PEEK Knotless Anchor
Company Name:	Stryker Endoscopy
510(k) #:	K232683

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 in skeletally mature pediatric and adult patients. The suture anchor systems thereby stabilize the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

VI. COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PRIMARY PREDICATE DEVICE

The following table represents a summary of the technological characteristics between the proposed and the primary predicate device. Although there are differences in the indications for use statements shown below, the subject device's IFU is consistent with the additional predicates.

	Proposed Device	Predicate Device
Manufacturer:	CONMED	CONMED
Device Name	Y-Knotless™ Flex Anchors	Y-Knotless™ Flex Anchors
510k Number	K261363	K253763
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 in skeletally mature pediatric and adult patients. The suture anchor systems thereby stabilize the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.	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. <i>The Y-Knotless™ Flex Anchors may be used in the following orthopedic procedures:</i> <i>1. Shoulder Labrum</i>

	Proposed Device	Predicate Device
		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-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.
How Supplied	Sterile Anchor w/Delivery System (1ea)	Sterile Anchor w/Delivery System (1ea)
Single Use /Reusable	Single-Use Only	Single-Use Only
Sterilization	Ethylene Oxide (10 ⁻⁶)	Ethylene Oxide (10 ⁻⁶)
Shelf-Life	3-Years	3-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
Materials	Implant/Anchor: UHMWPE Implant Suture: UHMWPE w/ green/white/black or white/black Non-Implant Shuttle Suture: UHMWPE with blue/ black	Implant/Anchor: UHMWPE Implant Suture: UHMWPE w/ green/white/black or white/black Non-Implant Shuttle Suture: UHMWPE with blue/ black

	Proposed Device	Predicate Device
	Driver: Shaft – SS Handle – ABS	Driver: Shaft – SS Handle – ABS
Packaging	Packaged as a single-unit device	Packaged as a single-unit device
Design	Folded flat suture, push-in, knotless splice loop	Folded flat suture, push-in, knotless splice loop
MR Compatibility	MR Safe	MR Safe
Instrumentation	Drill Guides Drill Bit Obturators	Drill Guides Drill Bit Obturators
Performance Testing	Cyclic Loading Insertion Fixation/Pull out	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

Insertion

Ultimate Pull Out Resistance

Cyclic Pull Displacement Resistance

Validation

User Validation

Packaging and Labeling User Validation

Transportation

Sterilization

Well-established Method Testing

Pyrogen (Bacterial Endotoxin)

Biocompatibility

Shelf-life

VIII. CONCLUSION

The Y-Knotless™ Flex Anchors are substantially equivalent in design, materials, intended use, principles of operation, sterilization, biocompatibility, and technical characteristics to the predicate Y-Knotless™ Flex Anchors (K253763). Based upon testing, the differences in the

proposed and predicate present no new issues, and the Y-Knotless™ Flex Anchors are substantially equivalent to the predicate device.