



June 18, 2025

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

Re: K251530

Trade/Device Name: CONMED Argo Knotless® Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 16, 2025
Received: May 19, 2025

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
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

510(k) Number (if known)

K251530

Device Name

CONMED Argo Knotless® Anchor

Indications for Use (Describe)

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

The CONMED Argo Knotless® Anchor 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K251530
510(k) SUMMARY

CONMED Corporation
CONMED Argo Knotless® Anchor

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 K251530.

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: May 16, 2025

II. DEVICE NAME

Device Name:	CONMED Argo Knotless® Anchor
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 MARKETING DEVICE

Device Name:	Argo Knotless™ SP Anchor
Company Name:	CONMED Corporation
510(k) #:	K220757

REFERENCE DEVICE/ LEGALLY MARKETING DEVICE

Device Name:	Argo Knotless® GENESYS™ Anchor
Company Name:	CONMED Corporation
510(k) #:	K244025

IV. DEVICE DESCRIPTION

The CONMED Argo Knotless® Anchor is an implantable bone anchor, that is supplied single use, sterilized via ethylene oxide (ETO) to a SAL of 10^{-6} . The threaded anchor and the suture eyelet are manufactured of PolyEtherEtherKetone (PEEK) material. Each size features a single use driver, a threaded anchor, suture eyelet, a 1.0mm UHMWPE Hi-Fi™, non-absorbable retention suture, and loader tab. The retention suture holds the PEEK eyelet in place on the driver and can be incorporated into the repair if desired. A maximum of six (6) Hi-Fi #2 suture, or

1.3mm Hi-Fi ribbon suture, or (2) two limbs of Hi-Fi tape, or one (1) bioresorbable reinforced implant can be threaded through the eyelet. The repair sutures are then tensioned and cleated on the driver cleat, if deemed necessary by the surgeon. These anchor configurations require a pre-prepared bone hole which can be created with 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 CONMED Argo Knotless[®] Anchor 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 tissue, in conjunction with appropriate postoperative immobilization throughout the healing period.

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
	CONMED	CONMED
Device Name	CONMED Argo Knotless [®] Anchor	Argo Knotless [™] SP Anchor
510k Number	TBD	K220757
Intended Use/Indications for Use	The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures. The CONMED Argo Knotless[®] Anchor 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.	The non-absorbable suture anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures. The Argo Knotless[™] SP Anchor 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 tissue, in conjunction with appropriate postoperative immobilization throughout the healing period.
Contraindications	1. Pathological conditions of bone which would adversely affect the Argo Knotless anchors. 2. Pathological conditions in the soft tissue to be repaired or reconstructed	1. Pathological conditions of bone which would adversely affect the Argo Knotless[™] SP anchors. 2. Pathological conditions in the soft tissue to be repaired or reconstructed

	Proposed Device	Predicate Device
	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. Direct attachment of artificial ligaments or other implants except for bioresorbable reinforced 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.	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. Direct 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.
How Supplied	Same	Sterile Anchor w/Delivery System (1ea)
Single Use /Reusable	Same	Single-Use Only
Sterilization	Same	Device sterilized via Ethylene Oxide Sterilization - SAL (10 ⁻⁶)
Shelf-Life	Same	18-months
Principle of Operation	Same	Non-absorbable suture anchors for soft tissue to bone fixation
Biocompatibility	Same	In accordance with ISO 10993-1 and FDA# G95-1
Packaging	Same	Packaged as a single unit device
Instrumentation	Same with the addition of a bone Tap, Smooth Punch, Tapered Broaching Punch, Reamer and Drill Guide	Reusable Bone Punch Sterile Disposable Bone Punch Drill Bit
Suture	Same	White UHMWPE, with polyester dyed with D&C Blue #6
Materials	Same with a Peek tip	Anchor: Titanium Tip; PEEK Suture: White, UHMWPE with polyester dyed with D&C Blue #6 Driver: Stainless Steel

	Proposed Device	Predicate Device
		Driver Handle: Polycarbonate, ABS, Radel Threader: ABS, nitinol, stainless steel
Design	Non-self-punching anchor	Self-punching anchor
MR Compatibility	MR Safe	MR Conditional
Performance Testing	Same	Reliability Cyclic Loading Insertion Fixation
Use with resorbable implant	Yes-Specific SKU	Not applicable

VII. **PERFORMANCE DATA**

Testing has been completed to demonstrate that CONMED Argo Knotless® Anchor performs as intended and is substantially equivalent to the predicate device. Completed testing includes the following:

Performance Testing

Insertion

Ultimate Pull Displacement Resistance

Cyclic

Validation

User Validation

Packaging (Transportation and Shelf-life)

Packaging and Labeling User Validation

Sterilization

Transportation

Well-established Method Testing

Pyrogen (Bacterial Endotoxin)

Biocompatibility

Shelf-life

VIII. CONCLUSION

The CONMED Argo Knotless[®] Anchor is either substantially equivalent or identical in intended use, principles of operation, performance testing results, materials, packaging, sterilization method, and biocompatibility as the predicate Argo Knotless[™] SP Anchor. Based upon the findings of our performance testing, the differences present no new issues of safety and effectiveness, and the CONMED Argo Knotless[®] Anchors are substantially equivalent to the predicate device, Argo Knotless[™] SP Anchors (K220757).