January 28, 2025

ConMed Corporation
Dionne Sanders
Sr. Manager, Regulatory Affairs
525 French Road
Utica, New York 13502

Re: K244025
Trade/Device Name: Argo Knotless GENESYS Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: December 24, 2024
Received: December 27, 2024

Dear Dionne 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 (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 Ferriera, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K244025

Device Name

Argo Knotless® GENESYS™ Anchor

Indications for Use *(Describe)*

Argo Knotless® GENESYS™ Anchor
The biocomposite suture anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures.

The Argo Knotless® GENESYS™ 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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510(k) SUMMARY
Argo Knotless® GENESYS ™ 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 for K244025.

I. SUBMITTER

Manufacturer:
CONMED Corporation
525 French Road
Utica, NY 13502

Official Contact Person:
Dionne Sanders, JM, MS, CQA, RAC
525 French Road
Utica, NY 13502
(O) 813-997-8126

Date Prepared: December 24, 2024

II. DEVICE NAME

Device Name:	Argo Knotless® GENESYS ™ Anchor
Classification Name:	Fasteners, Fixation, Biodegradable, Soft Tissue Fasteners, Fixation, Nondegradable, Soft Tissue
Regulatory Class:	Class II, per 21 CFR Part 888.3030; 888.3040
Product Codes:	MAI, MBI

III. PREDICATE DEVICE

Device Name:	Argo Knotless® GENESYS ™ SP Anchor, models SPKx Argo Knotless® GENESYS ™ Anchor, models KBCx
Company Name:	CONMED Corporation
510(k) #:	K240090

IV. DEVICE DESCRIPTION

Argo Knotless® GENESYS ™ Anchor: The Argo Knotless® GENESYS™ 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 is manufactured of bioabsorbable material, and the suture eyelet is manufactured of PEEK Optima material. The device features a single use driver, a threaded anchor, a PEEK-Optima eyelet, a #2 UHMWPE, 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. The suture eyelet can hold up to six (6) sutures or one (1) bioresorbable reinforced implant. These anchor configurations require a pre-prepared bone hole which can be created with Class I, Exempt instrumentation.

V. INTENDED USE/ INDICATIONS FOR USE

Argo Knotless® GENESYS™ Anchor
The biocomposite suture anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures.

The Argo Knotless® GENESYS™ 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.

VI. COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A summary of the technological characteristics between the proposed and the predicate device is provided.

	Proposed Device	**Predicate Device**
	Argo Knotless® GENESYS™ Anchor	Argo Knotless® GENESYS™ Anchor
510k Number	**K244025**	**K240090**
Intended Use/Indications for Use	Same	Argo Knotless® GENESYS™ Anchor The biocomposite suture anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures. The Argo Knotless® GENESYS™ 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.
Contraindications	1. Pathological conditions of bone which would adversely affect the Argo Knotless® GENESYS™ 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	1. Pathological conditions of bone which would adversely affect the Argo Knotless® GENESYS™ 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. Direct attachment of artificial ligaments or other implants.

	Proposed Device	Predicate Device
	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.	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 on a delivery driver
Single Use /Reusable	Same	Single-Use Only
Sterilization	Same	ETO
Shelf-Life	Same	18-months
Principle of Operation	Same	Soft tissue to bone fixation
Biocompatibility	Same	In accordance with ISO 10993-1 and FDA# G95-1
Design	Non-self-punching anchor	Self-punching anchor Non-self-punching anchor Non-self-punching, fully loaded anchor
Packaging	Same	Packaged as a single-unit device
Instrumentation	Same, with addition of reamer and drill guide	Class 1, Exempt instrumentation for initiating a bone hole.
Use with resorbable implant	Yes	Specific SKU

VII. PERFORMANCE DATA

Testing and analysis have been completed to demonstrate that the Argo Knotless® GENESYS™ Anchor performs as intended and is substantially equivalent to the predicate device. Additional evaluation for this modification includes the following.

- Performance Testing (Insertion, Cyclic and Ultimate Pull Displacement Resistance)
- User Validation (Cadaver Medial Collateral Ligament/Lateral Collateral Ligament)
- Packaging and Labeling User Validation

VIII. CONCLUSION

The Argo Knotless® GENESYS™ Anchor is substantially equivalent in design, intended use, performance, and fundamental principle of operation. There are no additional questions of safety and effectiveness.