March 5, 2024

CONMED Corporation
Dionne Sanders, MS, CQA, RAC
Senior Manager, Regulatory Affairs
Orthopedics Division
525 French Road
Utica, New York 13502

Re: K240090
Trade/Device Name: Argo Knotless GENESYS Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: January 10, 2024
Received: January 12, 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.

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,

Sara S. Thompson -S

For

Jesse Muir, Ph.D.
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)*

K240090

Device Name

Argo Knotless GENESYS Anchor

Indications for Use *(Describe)*

Argo Knotless® GENESYS™ SP Anchor

The biocomposite suture anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures. The Argo Knotless® GENESYS™ 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 soft tissue, in conjunction with appropriate postoperative immobilization throughout the healing period.

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.**

510(k) SUMMARY
Argo Knotless® GENESYS ™ SP Anchor
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 of Safety and Effectiveness for 510(k) Number - **K240090.**

I. **SUBMITTER**

Manufacturer:
CONMED Corporation
525 French Road
Utica, NY 13502

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

Date Prepared: March 1, 2024

II. **DEVICE NAME**

| | |
|---|---|
| Device Name: | Argo Knotless® GENESYS ™ SP Anchor, models SPKx<br>Argo Knotless® GENESYS ™ Anchor, models KBCx |
| Classification Name: | Fasteners, Fixation, Biodegradable, Soft Tissue<br>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™ SP Anchors |
| Company Name: | CONMED Corporation |
| 510(k) #: | K220757 |

**REFERENCE DEVICE**

| | |
|---|---|
| Device Name: | CrossFT Knotless Biocomposite Suture Anchor with Disposable Driver |
| Company Name | CONMED Corporation |
| 510(k)#: | K170501 |

IV. **DEVICE DESCRIPTION**

Argo Knotless® GENESYS ™ SP Anchor: The Self-Punching (SP) Argo Knotless® GENESYS™ Anchor is an implantable bone anchor, that is supplied for single use, sterilized via ethylene

oxide (ETO) to a SAL of $10^{-6}$. The threaded anchor is manufactured of bioabsorbable material, and the broaching tip (suture eyelet) is manufactured of titanium material. Each size features a single-use driver, the threaded anchor, a Titanium suture eyelet, a UHMWPE 1.0mm non-absorbable retention suture, and loader tab. The retention suture holds the titanium eyelet in place on the driver assembly and can be incorporated into the repair if desired. The suture eyelet can hold up to six (6) sutures.

Argo Knotless® GENESYS ™ Anchor: The Non-Self-Punching 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 anchor configuration requires a pre-prepared bone hole. The threaded anchor is manufactured of bioabsorbable material, and the suture eyelet is manufactured of PEEK material. Each size features a single use driver, a threaded anchor, a PEEK suture 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. These anchor configurations require a pre-prepared bone hole which can be created with Class I, Exempt instrumentation.

Argo Knotless® GENESYS ™ Anchor: The Preloaded 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 material. The eyelet is held on with a #2 UHMWPE, non-absorbable retention suture and supplied with either a white/black or blue/blue colored non-absorbable Hi-Fi suture tape, a retention suture, and loader tab. These anchor configurations require a pre-prepared bone hole which can be created with Class I, Exempt instrumentation.

Principle of Operation – soft tissue to bone fixation

V. **INTENDED USE/ INDICATIONS FOR USE**

Argo Knotless® GENESYS™ SP Anchor

The biocomposite suture anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures.

The Argo Knotless® GENESYS™ 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 soft tissue, in conjunction with appropriate postoperative immobilization throughout the healing period.

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™ SP Anchor |
| **510k Number** | TBD | **K220757** |
| **Intended Use/Indications for Use** | Argo Knotless® GENESYS™ SP Anchor<br>The biocomposite suture anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures.<br><br>The Argo Knotless® GENESYS™ 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 soft tissue, in conjunction with appropriate postoperative immobilization throughout the healing period.<br><br>Argo Knotless® GENESYS™ Anchor<br>The biocomposite suture anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures. | The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures.<br><br>The CONMED Argo Knotless™ SP 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 system thereby stabilizes the damaged tissue, in conjunction with appropriate postoperative immobilization throughout the healing period. |

| | Proposed Device | Predicate Device |
|---|---|---|
| | 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. | |
| **How Supplied** | Sterile Anchor on a delivery driver | |
| **Single Use /Reusable** | Single-Use Only | |
| **Sterilization** | Device sterilized via Ethylene Oxide Sterilization - SAL ($10^{-6}$) | |
| **Shelf-Life** | 18-months | |
| **Principle of Operation** | Soft tissue to bone fixation | |
| **Biocompatibility** | In accordance with ISO 10993-1 and FDA# G95-1 | |
| **Dimensions (Diameter X Length)** | 4.75mm X 11.5”<br>5.5mm X 11.5” | 4.75mm X 11.5”<br>5.5mm X 11.5” |
| **Design** | (1) Self-punching anchor<br>(2) Non-self-punching anchor<br>(3) Non-self-punching, fully loaded anchor | Self-punching anchor |
| **Packaging** | Packaged as a single-unit device | |
| **Instrumentation** | Class 1, Exempt instrumentation for initiating a bone hole. | |
| **Suture** | White/Blue: White Hi-Fi non-absorbable braided, UHMWPE ribbon with polyester tracer and D&C Blue #6<br><br>Black #2 Suture: UHMWPE with 1% black (D&C Black #4) colorant<br><br>White/Blue/Black #2 Suture: White UHMWPE, silicone coated multifilament nylon tracer with black | White UHMWPE, with polyester dyed with D&C Blue #6 |

| | Proposed Device | Predicate Device |
|---|---|---|
| | (logwood) colorant and multifilament polyester tracer with D&C blue no. 6 colorant.<br><br>Blue/Black #2 Suture: UHMWPE with blue (chromium-cobalt aluminum-oxide) and black with D&C Black #4) colorants<br><br>White/Black Tape: White UHMWPE with a silicone coated multifilament nylon tracer with black (logwood) colorant.<br><br>Blue/Blue Tape: UHMWPE with D&C blue no. 6 colorant and multifilament polyester tracer with D&C blue no. 6 colorant. | |
| **Materials** | Anchor: Bioabsorbable threaded anchor with either a PEEK, or Titanium Tip.<br>Suture: see suture section<br>Driver: Stainless Steel<br>Driver Handle: Polycarbonate, ABS, Radel<br>Threader: ABS, nitinol, stainless steel | Anchor: Titanium Tip; PEEK<br>Suture: see suture section<br>Driver: Stainless Steel<br>Driver Handle: Polycarbonate, ABS, Radel<br>Threader: ABS, nitinol, stainless steel |
| **MR Compatibility** | MR Conditional<br>MR Safe | MR Conditional |
| **Performance Testing** | Reliability<br>Cyclic Loading<br>Insertion<br>Fixation | |

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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.

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|---|---|
| • Performance Testing<br>• Transportation<br>• Shelf-life | • Magnetic Resonance<br>• Corrosion Susceptibility<br>• Pyrogen (Bacterial Endotoxin) testing plan |

| | |
|---|---|
| • Biocompatibility<br>• Packaging (Transportation and Shelf-life)<br>• Sterilization<br>• User Validation<br>• Packaging and Labeling User Validation | • Degradation |

VIII. **CONCLUSION**

The Argo Knotless® GENESYS™ Anchor is substantially equivalent in design, intended use, performance testing, transportation, packaging, biocompatibility, sterilization, shelf-life, and principle of operation. The technological differences in materials of manufacture, and the various anchor configurations do not raise any questions of safety and effectiveness and is as safe and effective as the legally marketed predicate device.