May 13, 2022

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

Re: K220757
Trade/Device Name: Argo Knotless™ SP Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: March 10, 2022
Received: March 15, 2022

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 (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 located 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.

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 803) for

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

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

For:

Laura C. Rose, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220757

Device Name
Argo Knotless™ SP Anchor

Indications for Use *(Describe)*
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.

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.

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510(k) SUMMARY

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 K220757.

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: May 13, 2022

II. DEVICE NAME

Device Name:	Argo Knotless™ SP Anchor
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:	CrossFT Knotless Suture Anchor
Company Name:	CONMED Corporation
510(k) #:	K163258

IV. DEVICE DESCRIPTION

The Argo Knotless™ SP Anchor is a soft tissue to bone fixation device that consists of a titanium tip with an eyelet to thread suture through, and a threaded anchor body, manufactured of PEEK material. The anchor design includes a 1.0mm UHMWPE Hi-Fi™ retention ribbon which secures the titanium tip to the delivery system and to the retention suture cleat.

V. INTENDED USE/ INDICATIONS FOR USE

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.

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	
Device Name	Argo Knotless™ SP Anchor	CrossFT Knotless Suture Anchor
510k Number	TBD	**K163258**
Intended Use/Indications for Use	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.	The CrossFT Knotless Suture Anchor with Disposable Driver is intended to reattach soft tissue to bone in orthopedic surgical procedures. The device may be used in either arthroscopic or open 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™ SP 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	1. Pathological conditions of bone which would adversely affect the CrossFT Knotless Suture 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

	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.	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.
How Supplied	Sterile Anchor w/Delivery System (1ea)	
Single Use /Reusable	Single-Use Only	
Sterilization	Device sterilized via Ethylene Oxide Sterilization - SAL (10^{-6})	
Shelf-Life	18-months	
Principle of Operation	Non-absorbable suture anchors for soft tissue to bone fixation	
Biocompatibility	In accordance with ISO 10993-1 and FDA# G95-1	
Packaging	Packaged as a single unit device	
Instrumentation	Reusable Bone Punch Sterile Disposable Bone Punch Drill Bit	
Suture	White UHMWPE, with polyester dyed with D&C Blue #6	• Black suture, Nylon with logwood extract • Blue suture, polyester per with D&C Blue #6, silicone coating • Blue Suture, UHMWPE, dyed with D&C Blue #6
Materials	Anchor: Titanium Tip; PEEK Suture: White, UHMWPE with polyester dyed with D&C Blue #6 Driver: Stainless Steel Driver Handle: Polycarbonate, ABS, Radel Threader: ABS, nitinol, stainless steel	Anchor: PEEK Suture: UHMWPE, Nylon, polyester Driver Shaft and Tip: 17-7 Stainless Steel; 465 Stainless Steel Handle and Knob: Polycarbonate Threader: Polycarbonate, Nitinol
MR Compatibility	MR Conditional	MR Safe

Performance Testing	Reliability Cyclic Loading Insertion Fixation

VII. PERFORMANCE DATA

Testing has been completed to demonstrate that the Argo Knotless™ SP Anchor performs as intended and is substantially equivalent to the predicate device. Bacterial endotoxin testing was conducted and met the endotoxin limits. Completed testing includes the following:

Performance Testing
Reliability
Ultimate Fixation Strength
Insertion Torque
Cyclic Testing

Validation
User Validation
Packaging and Transportation
Labeling
Sterilization

Well-established Method Testing
Pyrogen (Bacterial Endotoxin)
Biocompatibility
Shelf-life
MR Safety Testing

VIII. CONCLUSION

The Argo Knotless™ SP 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 CrossFT Knotless Suture Anchors. Based upon the findings of our performance testing, the differences present no new issues of safety and effectiveness, and the Argo Knotless™ SP Anchors are substantially equivalent to the predicate device, CrossFT Knotless Suture Anchors (K163248).