May 13, 2022

CONMED Corporation
Orjada Dervishleri
Regulatory Affairs Specialist
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K220186
Trade/Device Name: Zone Specific AIM™ Device
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT, MBI
Dated: February 12, 2022
Received: February 14, 2022

Dear Orjada Dervishleri:

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)*

K220186

Device Name
Zone Specific AIM™

Indications for Use *(Describe)*
The Zone Specific AIM™ Device is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repairs, including repair of meniscal tears.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 K220186.

I. SUBMITTER

CONMED Corporation
11311 Concept Blvd
Largo, Florida 33773

Phone: 727-392-6464

Contact Person: Orjada Dervishleri
Date Prepared: May 13th, 2022

II. DEVICE NAME

Device Name:	Zone Specific AIM™ Device
Classification Name:	Suture, Nonabsorbable, Synthetic, Polyethylene
Regulatory Class:	Class II, per 21 CFR Part 878. 5000
Product Codes:	GAT, MBI

III. PREDICATE/ LEGALLY MARKETED DEVICE

Device Name:	ConMed Linvatec Sequent™ Meniscal Repair Device
Company Name:	ConMed Linvatec
510(k) #:	K102339

IV. DEVICE DESCRIPTION

The Zone Specific AIM™ is an all-inside meniscal repair device that sequentially deploys implants and suture. The device is composed of peek implants and ultra-high molecular weight polyethylene (UHMWPE) suture (Hi-Fi). The handheld, disposable device, provided sterile for single use, is removed at the end of the repair leaving behind a suture/implant construct. The anchor, suture, and disposable handheld device are EO Sterilized.

V. INTENDED USE/ INDICATIONS FOR USE

The Zone Specific AIM™ Device is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repairs, including repair of meniscal tears.

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.

	Zone Specific AIM™ Device Proposed Device	Sequent™ Meniscal Repair Device Predicate Device
Device Description	The Zone Specific AIM™ is an all-inside meniscal repair device that sequentially deploys implants and suture. The device is composed of peek implants and ultra-high molecular weight polyethylene (UHMWPE) suture (Hi-Fi). The handheld, disposable device, provided sterile for single use, is removed at the end of the repair leaving behind a suture/implant construct. The anchor, suture, and disposable handheld device are EO Sterilized.	The ConMed Linvatec Sequent™ Meniscal Repair Device is an all-inside meniscal repair device that sequentially deploys implants and suture. This device allows the surgeon to generate multiple stitches in order to create fixation points along a soft tissue tear. The hand held, disposable device, provided sterile for single use, is removed at the end of the repair leaving behind a suture/implant construct. The implant encompasses a cleat which retains the suture and allows the knotless feature.
Intended Use / Indications for use	The Zone Specific AIM™ Device is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repairs, including repair of meniscal tears.	The ConMed Linvatec Sequent™ Meniscal Repair Device is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repairs, including the repair of meniscal tears.
Contraindications	1. Insufficient quantity or quality of tissue. 2. Blood supply limitations and/or previous infections, which may tend to retard healing. 3. Patients with active sepsis or infection. 4. Conditions which tend to limit the patient's ability or willingness to follow directions during the healing period. 5. Foreign body sensitivity, known or suspected allergies to implant and/or instrument materials. 6. Soft tissue tears which would not be appropriate to repair.	
Components	Anchor Suture Shaft Handle Protective sleeve	
Technological Characteristics	All-Inside Implant Pretied Adjustable Sleeve Two (2) implant configurations Polyethylene suture / Peek Implant Stitch Repair Multiple needle access/curves (25° Curved; 15° Reverse) Suture management wheel EtO Sterilization	Identical Not pretied Manually adjusted depth sheath Multiple Implant configuration Identical Identical Multiple needle access (straight; curved) Identical Identical

VII. PERFORMANCE DATA

Testing has been completed to demonstrate that the Zone Specific AIM™ 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:

Verification Testing

- Reliability
- Ultimate Fixation Strength
- Transportation
- Cyclic
- Pyrogen
- Biocompatibility
- Shelf-life
- MR Safety Testing

Validation Testing

- User Validation
- Packaging
- Labeling
- Sterilization

VIII. CONCLUSION

The Zone Specific AIM™ Device is either substantially equivalent or identical in design, materials, intended use, principles of operation, and technical characteristics to the predicate Sequent™ Meniscal Repair Device. Based upon the findings of our performance testing, the differences present no new issues of safety and efficacy, and the Infinity™ Fixation System is substantially equivalent to the Sequent™ Meniscal Repair Device (K102339).