January 22, 2019

ConMed Corporation
Jeremy Walter
Regulatory Affairs Specialist
525 French Road
Utica, New York 13502

Re: K182955
Trade/Device Name: EZStart™ Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 22, 2018
Received: October 24, 2018

Dear Mr. Walter:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K182955

Device Name
EZStart™ Interference Screw

Indications for Use *(Describe)*

Intended Use

EZ Start™ Interference Screws are intended for use in bone - tendon - bone graft fixation in anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction of the knee.

Indications for Use

EZ Start™ Interference Screws are used to provide bone fixation in orthopedic procedures, including bone-tendon-bone graft fixation in anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction of the knee.

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

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 K182955.

I. SUBMITTER

CONMED Corporation
11311 Concept Blvd
Largo, Florida 33773

Phone: 727-399-5418
Fax: 727-399-5264

Contact Person: Jeremy Walter
Date Prepared: December 21, 2018

II. DEVICE NAME

Device Name:	EZStart™ Interference Screw
Common Name:	Bone Screw
Classification Name:	Screw, Fixation, Bone
Regulatory Class:	Class II, per 21 CFR Part 888. 3040
Product Codes:	HWC

III. PREDICATE/ LEGALLY MARKETED DEVICE

Device Name:	Concept Cannulated Interference Screw
Company Name:	Linvatec Corporation
510(k) #:	K933352

IV. REFERENCE DEVICE

Device Name:	Guardsman® Interference Screws
Company Name:	Linvatec Corporation
510(k) #:	K960962

V. DEVICE DESCRIPTION

The EZStart™ Interference Screw is a dual threaded titanium interference screw with a tapered tip for easy insertion into bone. The screw is cannulated to allow a guidewire through to assist with placement of the screw into the bone tunnel. The screw is used to maintain the fixation of bone – tendon – bone grafts in orthopedic procedures. The device is Gamma Sterilized.

VI. INTENDED USE/ INDICATIONS FOR USE

Intended Use:
EZ Start™ Interference Screws are intended for use in bone - tendon - bone graft fixation in anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction of the knee.

Indications for Use
EZ Start™ Interference Screws are used to provide bone fixation in orthopedic procedures, including bone-tendon-bone graft fixation in anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction of the knee.

VII. 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.

	EZStart™ Interference Screw Proposed Device	Concept Cannulated Interference Screw Predicate Device
Device Description	A sterile cannulated titanium interference bone screw.	Same
Intended Use	Intended for use in bone - tendon - bone graft fixation in anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction of the knee.	Same, excluding PCL.
Indication for Use	Used to provide bone fixation in orthopedic procedures, including bone-tendon-bone graft fixation in anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction of the knee.	Same, excluding PCL.
Contraindications	1. Insufficient quantity or quality of bone for attachment. 2. Blood supply limitations and/or previous infections which may retard healing. 3. Foreign-body sensitivity - where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation. 4. Patients with active sepsis or Infection. 5. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.	Same
Device Dimensions	Lengths: 15mm – 30mm Diameters: 6mm – 10mm	Same, excluding 15 mm lengths and 10 mm diameters.
Technological Characteristics	Metallic dual-threaded screw-in design	Same

VIII. PERFORMANCE DATA

Testing has been completed to demonstrate that the EZStart™ Interference Screw performs as intended and is substantially equivalent to the predicate device.

Completed testing includes the following:

Verification Testing

- Insertion Torque
- Fixation Strength
- Sterilization
- Biocompatibility
- Pyrogenicity
- Shelf-life
- Post Aging Functional
- Transportation
- MR Safety

Validation Testing

- Device User Validation
- Packaging/Labeling User Validation

Pyrogenicity testing was conducted using a Limulus Amebocyte Lysate (LAL) method with results that met the current FDA and USP requirements, < 0.5 EU/mL and < 20 EU/device, respectively.

IX. CONCLUSION

The EZStart™ Interference Screw is either substantially equivalent or identical in design, materials, intended use, principles of operation, and technical characteristics to the predicate Concept Cannulated Interference Screw. Based upon the findings of our performance testing, the differences present no new issues of safety and efficacy, and the EZStart™ Interference Screw is substantially equivalent to the Concept Cannulated Interference Screw (K933352).