June 28, 2024

CC-Instruments Inc
% Mason Makulinski
Project Engineer
Jalex Medical
27865 Clemens Rd Suite 3
Westlake, Ohio 44145

Re: K232780
Trade/Device Name: CC-Clip® Implant System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN

Dear Mason Makulinski:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on December 18, 2023. Specifically, FDA is updating this SE Letter because FDA inadvertently indicated that the SE determination also included review and clearance of a predetermined change control plan (PCCP). However, your 510(k) submission did not include a PCCP, so FDA is providing this administrative correction. Please see the attached revised clearance letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Limin Sun, OHT6: Office of Orthopedic Devices, 301-796-7056, limin.sun@fda.hhs.gov.

Sincerely,

Christopher Ferreira -S

for

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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Re: K232780
Trade/Device Name: CC-Clip® Implant System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN
Dated: September 11, 2023
Received: September 11, 2023

Dear Mason Makulinski:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on December 18, 2023.

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,

Christopher Ferreira -S

for

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*

K232780

Device Name
CC-Clip® Implant System

Indications for Use *(Describe)*
The CC-Clip® device is intended as an adjunct in coracoclavicular ligament disruption repair.

Specifically, the CC-Clip® device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

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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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 Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the CC-Clip® Implant System.

Submitted By: CC-Instruments Inc.
850 New Burton Road, Suite 201
Dover, Delaware 19904

Date: 18DEC2023

Contact Person: Mason Makulinski, Project Engineer
Contact Telephone: (440) 242-9127
Contact Fax: (440) 933-7839

Device Trade Name: CC-Clip® Implant System

Common Name: Button/Suture
Device Classification Name: 21 CFR 888.3030, Single/multiple bone fixation appliances and accessories
Device Classification: Class II
Reviewing Panel: Orthopedic
Product Code: HTN

Primary Predicate Device: Arthrex TightRope® Acromioclavicular (AC) device (K052776)

Device Description:

CC-Clip® is an implantable device for an arthroscopic coracoclavicular (CC) ligament reconstruction and acromioclavicular (AC) ligament reconstruction technique. The original ligaments fail due to an AC joint separation and cause superior and posterior translation of the clavicle.

CC-Clip® device consists of a titanium implant on the clavicle, a titanium counterpart under the coracoid, and non-resorbable suture between the implants. A USP size 5 suture is not provided with CC-Clip®, but the Arthrex #5 FiberWire is recommended with the CC-Clip® device.

Instrumentation included with the CC-Clip® system includes two instruments: the CC-Clip® Straight Lasso guide and CC-Clip® Curved Lasso guide. Additional general-use, readily available instrumentation required for the CC-Clip® procedure includes lasso wire, guide pins, and drill bits which are to be supplied by the end user per the surgical technique. Both CC-Clip® guides are re-usable surgical instruments provided non-sterile to the user. The CC-Clip® implants are supplied sterile to the user and are single use.

Indications for Use:

The CC-Clip® device is intended as an adjunct in coracoclavicular ligament disruption repair.

510(k) Submission – CC-Clip® Implant System

Specifically, the CC-Clip® device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

Summary of Technological Characteristics:

The CC-Clip® Implant System is similar in its intended use to the predicate device, Arthrex TightRope® Acromioclavicular (AC) device System. The proposed devices are composed of two buttons that are fabricated from titanium alloy per ASTM F136, and the design features for the implant system are similar to the predicate device, including dimensions, shape, and sizes.

Performance Data – Nonclinical:

Substantial equivalence is supported by the results of mechanical testing including engineering analysis of static (ultimate load) and dynamic testing.

Table 6.1. Mechanical Testing Program for CC-Clip® Implant System

Verification Method	Results
Static Testing	Acceptable
Dynamic Testing	Acceptable

Testing performed on the CC-Clip® Implant System demonstrated that all performance-based requirements and acceptance criteria were met to support safety and effectiveness and is considered substantially equivalent to the predicate device.

Performance Data – Clinical:

Clinical testing is not required and therefore not conducted as part of this submission.

Substantial Equivalence:

The CC-Clip® Implant System has the same intended use and fundamental scientific technology as the Arthrex TightRope® Acromioclavicular (AC) device (K052776) primary predicate device. Both devices compare similarly in:

- Design features and instrumentation
- Intended use and indications for use
- Material composition
- Dimensions
- Function
- Sterilization methods

Refer to Table 8.2 below for additional information. The potential impact on substantial equivalence of each technological difference was addressed through risk analysis and verification and validation testing. Any differences between the CC-Clip® Implant System and the predicate device do not raise any questions of safety and effectiveness.

510(k) Submission – CC-Clip® Implant System

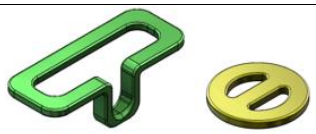
The table below summarizes the features of the subject device and its equivalence to the predicate device.

Table 8.2 Subject and Predicate Device Comparison

	Subject Device: CC-Clip® Implant System	**Predicate Device: Arthrex TightRope® Acromioclavicular (AC) device**
Regulation Name	Single/multiple component metallic bone fixation appliances and accessories	Single/multiple component metallic bone fixation appliances and accessories
Regulation Number	21 CFR 888.3030	21 CFR 888.3030
Product Code	HTN	HTN
Device Description	CC-Clip® is an implantable device for an arthroscopic coracoclavicular (CC) ligament reconstruction and acromioclavicular (AC) ligament reconstruction technique. The original ligaments fail due to an AC joint separation and cause superior and posterior translation of the clavicle. CC-Clip® device consists of a titanium implant on the clavicle, a titanium counterpart under the coracoid, and non-resorbable suture between the implants. Suture is not provided with CC-Clip®, but the Arthrex #5 FiberWire is recommended with the CC-Clip® device. Instrumentation included with the CC-Clip® system includes two instruments: the CC-Clip® Straight Lasso guide and CC-Clip® Curved Lasso guide. Additional general-use, readily available instrumentation required for the CC-Clip® procedure includes lasso wire, guide pins, and drill bits which are to be supplied by the end user per the surgical technique. Both CC-Clip® guides are re-usable surgical instruments provided non-sterile to the user. The CC-Clip® implants are supplied sterile to the user and are single use.	The TightRope™ Acromioclavicular (AC) Device is designed as two differently sized metal buttons, both stainless steel or both titanium, and FiberWire™ suture. The buttons are pre-threaded with FiberWire Suture, looped twice through the buttonholes. Pull-Through FiberWire sutures are also looped through each button. The TightRope™ Acromioclavicular (AC) Device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically, the Arthrex TightRope Acromioclavicular (AC) Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.
Indications for Use	The CC-Clip® device is intended as an adjunct in coracoclavicular ligament disruption repair.	The TightRope™ Acromioclavicular (AC) Device is intended as an adjunct in fracture repair involving metaphyseal and particular small bone

CC-CLIP

510(k) Submission – CC-Clip® Implant System

	Specifically, the CC-Clip® device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.	fragments where screws are not indicated and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically, the Arthrex TightRope Acromioclavicular (AC) Device is intended to provide fixation during syndesmotic trauma, such as fixation of acriomioclavicualr separations due to coracoclavicular ligament disruptions.
Device Model		
Material	Implants: Titanium Alloy Instruments: Stainless Steel	Implants: Titanium Alloy and stainless steel
Sterilization	Implants: Gamma Radiation Instruments: End User cleaning and steam sterilization	Unknown
Clavicle Clip Sizes	16mm and 20mm Length	Unknown
Coracoid Clip Sizes	10mm and 12mm Round 10mm and 12mm Rectangular	Unknown
Suture Size Indication	#5 Suture	#5 Suture

Conclusion:

The CC-Clip® Implant System is as safe and effective as its predicate device, as it has the same intended use, indication for use, material composition, design features, manufacturing method, sterilization method, performance requirements and principles of operation as the primary predicate device (K052776). The design differences do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. Non-clinical testing demonstrates that the CC-Clip® Implant System is substantially equivalent to the primary predicate device.