March 26, 2025

Arthrex Inc.
Ivette Galmez
Principal Regulatory Affairs Specialist
1370 Creekside Blvd.
Naples, Florida 34108

Re: K243995
Trade/Device Name: Arthrex Humeral Plating System and Cerclage Button
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, JDQ
Dated: December 23, 2024
Received: December 26, 2024

Dear Ivette Galmez:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Christopher Ferreira, M.S.
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)*

K243995

Device Name

Arthrex Humeral Plating System and Cerclage Button

Indications for Use *(Describe)*

The Humeral Plating System is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone.

The Cerclage Button is intended for use with the humeral plating system and FiberTape® cerclage suture, to augment fracture stabilization with humeral plates in long bone fixation. The cerclage button is designed for use with the humeral plating system and may not be used alone.

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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K243995
510(k) Summary

Date Prepared	12/23/2024
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Ivette Galmez Title: Principal Regulatory Affairs Specialist Phone: 239-643-5553, ext. 71263 Email: Ivette.galmez@arthrex.com
Trade Name	Arthrex Humeral Plating System and Cerclage Button
Common Name	Plate, Fixation, Bone Cerclage, Fixation
Product Code	HRS, JDQ
Classification Name	21 CFR 888.3030: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories 21 CFR 888.3010: Bone fixation cerclage
Regulatory Class	II
Primary Predicate Device	K180310: Depuy Synthes LCP Proximal Humerus Plate
Additional Predicate	K172975: Depuy Synthes Cerclage Positioning Pin
Reference Devices	K242079: Arthrex Elbow Fracture Plating System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Humeral Plating System and Cerclage Button.
Device Description	The Arthrex Humeral Plating and Cerclage Button consist of straight humeral plates and a 3.5 threaded cerclage button for use in the repair of proximal humerus fractures. The devices are provided sterile (gamma) and non-sterile, for single use. The proposed plates range in length from 90.5 - 309 mm and include suture holes for soft tissue refixation. The proposed devices are manufactured from titanium alloy conforming to ASTM F136. The proposed devices are compatible with Arthrex 3.5 mm screws (K241592 and K203294) and Arthrex 4.0 mm screws (K150456, K143614, and K103705).
Indications for Use	The Arthrex Humeral Plating System is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone. The Cerclage Button is intended for use with the humeral plating system and FiberTape® cerclage suture, to augment fracture stabilization with humeral plates in long bone fixation. The cerclage button is designed for use with the humeral plating system and may not be used alone.
Performance Data	Arthrex conducted 4-point bend (ASTM F382-17) testing to demonstrate that the Arthrex Humeral Plating System perform statistically equivalent to the primary predicate device Depuy-Synthes LCP Plates (K180310). MRI force, torque, and image artifact testing were conducted in accordance with FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, ASTM F2052 *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*, ASTM F2119 *Standard Test*

	Method for Evaluation of MR Image Artifacts from Passive Implants, ASTM F2182 *Standard Test Method for Measurement of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging* and ASTM F2213 *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*. Bacterial Endotoxins Test (BET) was performed on the Arthrex devices utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14. The testing conducted demonstrates that the sterile devices meet pyrogen limit specifications. Assessment of the physical product attributes including product, design, size, and materials has determined that the Arthrex Humeral Plating System and Cerclage Button do not introduce additional risks or concerns regarding sterilization and shelf-life.
Technological Comparison	The main differences with the predicates are provided below: • The indications for use for the proposed Cerclage Button are equivalent to the Depuy-Synthes Cerclage Positioning Pin (K172975), except that the indications for the proposed device have been updated to indicate that the cerclage button is an adjunct device for use only with the proposed Arthrex Humeral Plating System, and to include the recommended Arthrex suture for use. • The proposed humeral plates are manufactured from a titanium alloy that is a different from the predicate humeral plates (K180310). • The proposed humeral plates will be offered in lengths outside the predicate humeral plates (K180310) size range.
Conclusion	The Arthrex Humeral Plating System and Cerclage Button is substantially equivalent to the primary Depuy Synthes LCP Proximal Humerus Plate (K180310) and Depuy Synthes Cerclage Positioning Pin (K172975) in which the basic design features and intended use are the same. The proposed devices have the same fundamental scientific technology, and are made with equivalent materials, design configuration, and sterility availability. Any differences between the Arthrex Humeral Plating System and Cerclage Button, and the predicate devices are considered minor and do not raise different questions of safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the proposed devices are substantially equivalent to the currently marketed predicate devices.