March 3, 2026

Arthrex, Inc.
Osiris Rios
Senior Regulatory Affairs Specialist
1370 Creekside Blvd.
Naples, Florida 34108

Re: K260353
Trade/Device Name: Arthrex Humeral Plating System (Anatomic Humeral Plate) 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: February 2, 2026
Received: February 3, 2026

Dear Osiris Rios:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260353

Please provide the device trade name(s).

Arthrex Humeral Plating System (Anatomic Humeral Plate) and Cerclage Button

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Date Prepared	02/02/2026
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Osiris Rios Title: Senior Regulatory Affairs Specialist Phone: 239-643-5553, ext. 71263 Email: Osiris.Rios@arthrex.com
Trade Name	Arthrex Humeral Plating System (Anatomic Humeral Plate) 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	K243995: Arthrex Humeral Plating System and Cerclage Button
Additional Predicate Devices	K180310: Depuy Synthes LCP Proximal Humerus Plate
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance of the Arthrex Humeral Plating System (Anatomic Humeral Plate) and Cerclage Button.
Device Description	The Arthrex Humeral Plating (Anatomic Humeral Plate) and Cerclage Button consist of contoured humeral plates and a 4.5 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 92 - 265 mm and include suture holes for soft tissue repair. 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), Arthrex 4.0 mm screws (K150456, K143614, and K103705), and Arthrex 4.5 mm screws (K141735).

Indications for Use	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.
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, Arthrex Humeral Plating System and Cerclage Button (K243995). MRI force, torque, and image artifact testing was previously 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*. Arthrex determined that the proposed Arthrex Humeral Plating System (Anatomic Humeral Plate) and Cerclage Button device does not represent a new worst-case in terms of MR compatibility and will be adopted into the MRI labeling previously reviewed and accepted by FDA within primary predicate device, Arthrex Humeral Plating System and Cerclage Button (K243995). Assessment of the physical product attributes including product, design, size, and materials has determined that the Arthrex Humeral Plating System (Anatomic Humeral Plate) and Cerclage Button does not introduce additional risks or concerns regarding sterilization and shelf-life.
Technological Comparison	The proposed Arthrex Humeral Plating System (Anatomic Humeral Plate) and Cerclage Button have the same intended use/indications, fundamental scientific technology, materials, packaging method,

sterility, shelf-life and MRI safety labeling as the primary predicate Arthrex Humeral Plating System and Cerclage Button (K243995) and additional predicate device Depuy Synthes LCP Proximal Humerus Plate (K180310).

The differences with the predicates are provided below:

- **Design:**
    - The Anatomic Humeral Plate in the proposed Arthrex Humeral Plating System is contoured and curved whereas the lateral plate in the cleared primary predicate (K243995) and additional predicate (K180310) are straight.
    - The Anatomic Humeral Plate in the proposed Arthrex Humeral Plating System is designed with 3 to 15 screw hole configurations and in multiple lengths with the overall length of the plates ranging from 92mm to 265 mm whereas the lateral plate in the cleared primary predicate (K243995) is designed with 3 to 17 screw hole configurations and in lengths 90.5 – 309 mm. The lengths for the proposed Anatomic Humeral Plates are within the lengths range of the primary predicate (K243995). The additional predicate (K180310) has less holes configurations than the proposed device. The lengths for the proposed Anatomic Humeral Plates are within the length range of the additional predicate (K180310).
    - The Anatomic Humeral Plate in the proposed Arthrex Humeral Plating System accepts 4.5 mm cerclage buttons in the distal shaft whereas the lateral plate in the cleared primary predicate (K243995) accepts 3.5 mm cerclage buttons in the shaft.
    - In addition to the Arthrex 3.5 mm Variable Angle Locking (VAL) Screws, Reinforced (K241592), 3.5mm VAL KreuLock™ Screws, Reinforced (K241592), Arthrex 3.5mm Low Profile Screws, Cortical (K203294), Arthrex 4.0 mm Low Profile Screws, and Cancellous (K150456, K143614, K103705); the proposed Anatomic Humeral Plate, in 7-hole and longer configurations, the most distal shaft

	screw holes accept 4.5 mm cortical or locking low profile screws (K141735). • **Packaging:** The proposed Cerclage Button (4.5mm) is packaged in a double Nylon/Nylon pouch configuration whereas the Cerclage Button (3.5 mm) cleared under K243995 was packaged in a double Poly/Tyvek pouch. However, the double Nylon/Nylon pouch configuration used for the proposed 4.5 mm Cerclage Button is identical to the packaging configuration (double Nylon/Nylon pouch) used for the lateral plates in the primary predicate device (K243995). Based on the basic design features, device configuration, intended use, fundamental scientific technology, technological characteristics and the performance data provided in this Special 510(k), Arthrex has determined that the proposed Arthrex Humeral Plating System (Anatomic Humeral Plate) and Cerclage Button are substantially equivalent to the primary predicate and additional predicate devices cleared via K243995 and K180310, respectively. Any differences between the proposed and predicate devices are considered minor and do not raise different questions concerning safety and effectiveness.
Conclusion	The Arthrex Humeral Plating System (Anatomic Humeral Plate) and Cerclage Button is substantially equivalent to the predicate devices cleared under K243995 and K180310 in which the basic design features and intended use are the same. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the proposed device is substantially equivalent to the currently marketed predicate devices.