November 14, 2024

Arthrex Inc.
Stacy Valdez
Senior Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108

Re: K242079
Trade/Device Name: Arthrex Elbow Fracture Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: October 15, 2024
Received: October 15, 2024

Dear Ms. Valdez:

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,

Shumaya Ali, M.P.H.
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)*

K242079

Device Name

Arthrex Elbow Fracture Plating System

Indications for Use *(Describe)*

The distal humerus fracture plates and olecranon fracture plates are indicated for adult patients. The distal humerus and olecranon fracture plates are indicated for fixation of fractures of the humerus and ulna.

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.

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510(k) Summary

Date Prepared	11/13/2024
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Stacy Valdez Title: Principal Regulatory Affairs Specialist Phone: 1-239-643-5553, ext. 72010 Email: stacy.valdez@arthrex.com
Trade Name	Arthrex Elbow Fracture Plating System
Common Name	Plate, Fixation, Bone
Product Code	HRS
Classification Name	21 CFR 888.3030: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class	II
Predicate Device	K061352: PERI-LOC Periarticular Locked Plating System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Elbow Fracture Plating System.
Device Description	The Arthrex Elbow Fracture Plating System consists of a series of olecranon and distal humerus plates of varying lengths, thicknesses, and orientations. The proposed plates are contoured and may be available in left and right configurations, ranging from 73 mm to 294.37 mm in length, 1.93 mm to 5.51 mm in thickness, and 10.06 mm to 22 mm in width. Each plate provides locking screw fixation and may include suture holes for soft tissue refixation. The proposed plates are manufactured from stainless steel conforming to ASTM F138 or titanium alloy confirming to ASTM F136 (ISO 5832-3). The plates are sold sterile (Gamma) and non-sterile and are single-use.
Indications for Use	The distal humerus fracture plates and olecranon fracture plates are indicated for adult patients. The distal humerus and olecranon fracture plates are indicated for fixation of fractures of the humerus and ulna.
Performance Data	Arthrex conducted Finite Element Analysis and 4-point bend (ASTM F382-17) under static and dynamic conditions to demonstrate that the mechanical performance of the subject device is substantially equivalent to that of the predicate

	device PERI-LOC Periarticular Locked Plating System (K061352). Arthrex conducted packaging validation and 5-year real-time aging shelf-life testing to demonstrate that the smaller and larger packaging configurations are capable of maintaining and protecting the product and sterility of the device throughout the shipping and handling environment. The proposed packaging configurations met all the packaging testing acceptance criteria in conformance to ISO 11607 and applicable standards. 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 Elbow Fracture Plating System does not introduce additional risks or concerns regarding sterilization and shelf-life.
Technological Comparison	The Arthrex Elbow Fracture Plating System is substantially equivalent to the predicate devices cleared under the predicate device PERI-LOC Periarticular Plating System (K061352) in which basic design features, intended use,

	fundamental scientific technology, materials, plate configuration, and sterility are identical. <u>Indications for Use:</u> • The indications for use for the distal humerus fracture plates and olecranon fracture plates are equivalent to the predicate device PERI-LOC Periarticular Locked Plating System (K061352) except for the following: ○ The distal humerus fracture plates and olecranon fracture plates will be indicated for a subset of anatomical locations and will not include a pediatric patient population or osteopenic bone compared to predicate device PERI-LOC Periarticular Locked Plating System (K061352). The Arthrex Elbow Fracture Plating System will be offered in shorter and longer lengths than the predicate device PERI-LOC Periarticular Plating System (K061352). The Arthrex Elbow Fracture Plating System will be offered in a smaller and larger width than the predicate device PERI-LOC Periarticular Plating System (K061352). The Arthrex Elbow Fracture Plating System is offered in smaller and larger thickness than the predicate device PERI-LOC Periarticular Plating System (K061352). <u>Packaging:</u> • The non-sterile plates are packaged inside a Polyethylene Bag inside an inner Zip Lock Polyethylene Bag or a single Polyethylene bag. The proposed non-sterile plates are also packaged in a single Polypropylene tube. • The sterile plates are packaged in a double PETG blister tray with Tyvek lidding or a double Nylon/Nylon pouch. <u>Shelf-Life:</u> • The shelf-life of the non-sterile plates is unlimited.

	• The shelf-life of the proposed sterile plates is 5-years. The Arthrex Elbow Fracture Plating System was evaluated for MR Conditional labeling. The predicate devices cleared under the predicate device PERI-LOC Periarticular Plating System (K061352) were not evaluated for MR Conditional labeling. The Arthrex Elbow Fracture Plating System is substantially equivalent to the predicate device PERI-LOC Periarticular Plating System (K061352) with the same intended use and minor differences in design and function. Any differences between the Arthrex Elbow Fracture Plating System and the predicate device are considered minor and do not raise different questions of safety or effectiveness.
Conclusion	The Arthrex Elbow Fracture Plating System is substantially equivalent to the predicate devices cleared under K061352 in which the basic design features and intended use are the same. Any differences between the Arthrex Elbow Fracture Plating System and the predicate device 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 device is substantially equivalent to the currently marketed predicate device.