July 30, 2026

Arthrex, Inc.
Rebecca Homan
Manager, Regulatory Affairs
1370 Creekside Blvd.
Naples, Florida 34108

Re: K260624
Trade/Device Name: Arthrex Radial Head Replacement System
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: Class II
Product Code: KWI
Dated: June 29, 2026
Received: June 30, 2026

Dear Rebecca Homan:

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), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

Joseph P. Russell -S

for: Farzana Sharmin, PhD
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

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.	K260624

Please provide the device trade name(s).

Arthrex Radial Head Replacement System

Please provide your Indications for Use below.

The Arthrex Radial Head Replacement System is indicated for:

- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
  - a) joint destruction and/or subluxation visible on x-ray; and/or
  - b) resistance to conservative treatment.
- Primary replacement after fracture of the radial head.
- Symptomatic sequelae after radial head resection.
- Revision following failed radial head arthroplasty.

The Cobalt Chrome stems are intended to be free floating and the Titanium Alloy stems are intended to be press-fit.

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)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

Date Prepared	July 29, 2026
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Rebecca R. Homan Manager, Regulatory Affairs 239-643-5553 ex. 73429 Rebecca.Homan@Arthrex.com
Trade Name	Arthrex Radial Head Replacement System
Common Name	Prosthesis, Elbow, Hemi-, Radial, Polymer
Product Code	KWI
Classification Name	21 CFR 888.3170 Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class	II
Primary Predicate Device	K060731 – Wright Medical Evolve Modular Radial Head
Reference Device	K181513 – Arthrex PushLock Tenodesis Anchor K041858 – Acumed Anatomic Radial Head System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Radial Head Replacement System.
Device Description	The Arthrex Radial Head Replacement System is a stand-alone, fixed-axis radial head prostheses, consisting of a polished, concave CoCrMo (conforming to ASTM F1537/ISO 5832-12) radial head with interchangeable connection to a modular stem. There are two stem options. A press fit, grit-blasted option manufactured from titanium alloy Ti-6Al-4V ELI (ASTM F136-13/ISO 5832-3) to press-fit

	into the radial canal. A second option is a free floating stem manufactured from CoCrMo (conforming to ASTM F1537/ISO 5832-12) with a smooth surface to free float in the radial canal. The Arthrex Radial Head Replacement System will be used to address comminuted fractures of the radial head that cannot otherwise be treated with plates and screws for fusion of bone fragments. The devices within the Arthrex Radial Head Replacement System are provided sterile (Gamma) and are packaged in a dual-barrier configuration for single-use.
Indications for Use	The Arthrex Radial Head Replacement System is indicated for: • Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with: a) joint destruction and/or subluxation visible on x-ray; and/or b) resistance to conservative treatment. • Primary replacement after fracture of the radial head. • Symptomatic sequelae after radial head resection. • Revision following failed radial head arthroplasty. The Cobalt Chrome stems are intended to be free floating and the Titanium Alloy stems are intended to be Press-Fit.

Performance Data	Arthrex has conducted Taper Disassociation Testing (ASTM F2009-20), Fatigue Testing, Fretting Corrosion Analysis (ASTM F1875-98), and MRI Safety Testing (ASTM F2182, ASTM F2052, ASTM F2119, ASTM F2213) on the Arthrex Radial Head Replacement System comparing the results to the primary predicate, Wright Medical Evolve Modular Radial Head (K060731) and reference device, Acumed Anatomic Radial Head System (K041858) or the standard.
Technological Comparison	The Arthrex Radial Head Replacement System and the primary predicate, Wright Medical Evolve Modular Radial Head (K060731) and reference device, Acumed Anatomic Radial Head System (K041858) have similar technologies. Geometrical differences between the Arthrex Radial Head Replacement System and the primary predicate and reference devices are considered minor and do not raise different questions concerning safety or effectiveness.
Conclusion	The Arthrex Radial Head Replacement System is substantially equivalent to the primary predicate, Wright Medical Evolve Modular Radial Head (K060731) in which the basic design features and intended use are the same. Based on the indications for use, technological characteristics, and the data submitted, the Arthrex Radial Head Replacement System is substantially equivalent to the currently marketed primary predicate.