March 20, 2026

Arthrex Inc.
Tiffany Mentzel
Principal Regulatory Affairs Specialist
1370 Creekside Blvd
Naples, Florida 34108

Re: K252016
Trade/Device Name: Arthrex Humeral Nails
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: February 17, 2026
Received: February 18, 2026

Dear Tiffany Mentzel:

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.	K252016

Please provide the device trade name(s).

Arthrex Humeral Nails

Please provide your Indications for Use below.

The Arthrex Humeral Nail System is intended to treat stable and unstable proximal fractures of the humerus including two and three, and in some cases, four part humerus fractures. The Humeral Nail is also intended to treat proximal and distal one third fractures, midshaft fractures and pathological fractures.

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

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

510(k) Summary

Date Prepared	March 3, 2026
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Tiffany Mentzel Title: Principal Regulatory Affairs Specialist Phone: 239-566-5833 Email: tiffany.mentzel@arthrex.com
Trade Name	Arthrex Humeral Nails
Common Name	Rod, Fixation, Intramedullary and Accessories
Product Code	HSB
Classification Name	21 CFR 888.3020: Intramedullary Fixation Rod
Regulatory Class	II
Primary Predicate Device	K050241 AOS Humeral Nail
Additional Predicate Devices	K090478 AOS Proximal Humeral Nail K103002 Synthes MultiLoc Humeral Nailing System
Reference Predicate	K210792 AUXEIIN Humeral Nail System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Humeral Nail System which was previously cleared as the AOS Humeral Nail System under K050241.
Device Description	The Arthrex Humeral Nails were previously cleared as the AOS Humeral Nail system under K050241. The Arthrex Humeral Nail is a titanium humeral intramedullary nail that is designed to enter the humerus through the greater tuberosity. It consists of an intramedullary nail, proximal and distal locking screws, compression screw and an end cap.
Indications for Use	The Arthrex Humeral Nail System is intended to treat stable and unstable proximal fractures of the humerus including two and three, and in some cases, four-part humerus fractures. The Humeral Nail is also intended to treat proximal and distal one third fractures, midshaft fractures and pathological fractures.
Performance Data	To address the potential risk of decreased mechanical strength of the proposed Arthrex Humeral Nail System compared to the reference predicate Synthes MultiLoc Humeral Nail System (K103002), Arthrex conducted mechanical testing (static and dynamic four-point bend testing) in accordance with ASTM F1264-16. The proposed

	Arthrex Humeral Nail System performed equivalent to the Synthes Nail test mean for bending yield moment, ultimate bending moment, and bending structural stiffness. Fatigue four-point bend testing in accordance with ASTM F1264-16, Annex A3 was performed. Arthrex also conducted static torsional testing to evaluate and measure the torsion stiffness inherent to the design and material for the Arthrex Humeral Nail per ASTM F1264-16, Annex A2. The results show the acceptance criterion was met. To demonstrate that the components of the Arthrex Humeral Nail System are "MR Conditional", Arthrex has conducted the recommended non-clinical testing and in-vivo electromagnetic simulation per the FDA Guidance, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", which includes Magnetically Induced Displacement Force, Magnetically Induced Torque, Heating by RF Fields, and Image Artifact. The results were used to develop safe scanning conditions and guidelines for the Arthrex Humeral Nail System for an hour-long scanning session. Simulated in-vivo results determined that patients with these devices can safely be scanned according to the conditions and guidelines listed in the provided Directions for Use (DFU).
Technological Comparison	Since the original clearance on March 14, 2005 (K050241), there have been modifications that are incorporated into this submission. The proposed Arthrex Humeral Nails are being offered with a smaller and larger distal diameter (7.0 and 9.0 mm) than the 8.0 distal diameter submitted via K050241. The proximal diameter of 10.0 mm remains unchanged for all three (3) sizes. The nail length is being offered in sizes 15 – 30 cm which is identical to the predicate nail length offering of 15 -30mm. The proposed Arthrex Humeral Nail System has been evaluated for MR Safety; however, it was not evaluated for MR safety when it was originally cleared under additional predicate devices AOS Humeral Nail System, K050241. The proposed Arthrex Humeral Nail System will be labeled as MR Conditional Safety.

	The overall design and configuration of the proposed Arthrex Humeral Nail System, surgical technique, fundamental scientific technology, sterility, materials and manufacturing processes remain identical to the predicate device AOS Humeral Nails (K050241).
Conclusion	Based on the intended use, fundamental scientific technology, and the data provided in this Traditional 510(k), Arthrex has determined that Arthrex Humeral Nail System is substantially equivalent to the predicate device. Any differences between the proposed and predicate device are considered minor and do not raise questions concerning safety and effectiveness.