



January 13, 2025

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

Re: K243890

Trade/Device Name: Arthrex Intramedullary Nails
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: December 17, 2024
Received: December 18, 2024

Dear Stacy 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,

Farzana Sharmin -S

Digitally signed by Farzana
Sharmin -S
Date: 2025.01.13 16:54:32 -05'00'

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

Submission Number (if known)

K243890

Device Name

Arthrex Intramedullary Nails

Indications for Use (Describe)

The trochanteric nail is intended to treat stable and unstable proximal fractures of the femur including peritrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures. The long trochanteric nail is additionally indicated for subtrochanteric fractures, peritrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in osteoporotic bone of the trochanteric and diaphyseal areas, long subtrochanteric fracture, ipsilateral femoral fractures, proximal and distal non-unions and malunions and revisions procedures.

The ES trochanteric nail is intended to treat stable and unstable proximal fractures of the femur including peritrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures.

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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510(k) Summary

<i>Date Prepared</i>	01/13/2025
<i>Submitter</i>	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
<i>Contact Person</i>	Name: Stacy Valdez Title: Principal Regulatory Affairs Specialist Phone: 1-239-643-5553 ext. 72010 Email: stacy.valdez@arthrex.com
<i>Trade Name</i>	Arthrex Intramedullary Nails
<i>Common Name</i>	Rod, Fixation, Intramedullary and Accessories
<i>Product Code</i>	HSB
<i>Classification Name</i>	21 CFR 888.3020: Intramedullary Fixation Rod
<i>Regulatory Class</i>	II
<i>Predicate Device</i>	K230257: Arthrex Intramedullary Nails
<i>Reference Device</i>	K132217: Arthrex Compression FT Screws K233134: I.T.S. INS Proximal Femur Nail
<i>Purpose of Submission</i>	This Special 510(k) premarket notification is submitted to obtain clearance of the Anti-Rotation Screw, 5.0 x 115 mm as a line extension to the Arthrex Intramedullary Nails cleared within K230257.
<i>Device Description</i>	The Arthrex Anti-Rotation Screw, 5.0 x 115 mm is 5.0 mm in diameter and 15 mm in length. The Arthrex Anti-Rotation Screw, 5.0 x 115 mm is a line extension to the Anti-Rotation Screws cleared within Arthrex Intramedullary Nails (K230257). The Arthrex Anti-Rotation Screw, 5.0 x 115 mm is manufactured from Titanium Alloy conforming to ASTM F136. The Arthrex Anti-Rotation Screw, 5.0 x 115 mm is sold sterile and is single-use.
<i>Indications for Use</i>	The trochanteric nail is intended to treat stable and unstable proximal fractures of the femur including peritrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures. The long trochanteric nail is additionally indicated for subtrochanteric fractures, peritrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in osteoporotic bone of the trochanteric and diaphyseal areas, long subtrochanteric fracture, ipsilateral femoral fractures, proximal and distal non-unions and malunions and revisions procedures.

	<p>The ES trochanteric nail is intended to treat stable and unstable proximal fractures of the femur including peritrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures.</p>
<i>Performance Data</i>	<p>Arthrex conducted failure torque/insertion torque, and torsional yield strength testing in accordance with ASTM F543 (Specification and Test Methods for Metallic Bone Screws) was performed on the Arthrex Anti-Rotation Screw, 5.0 x 115 mm to address the potential risk of decreased mechanical strength.</p> <p>The Arthrex Anti-Rotation Screw, 5.0 x 115 mm was evaluated to ensure that the additional length would not represent a new worst-case in terms of MR compatibility and to justify that the previously determined MR Conditional labeling cleared within the primary predicate device Arthrex Intramedullary Nails (K230257) is appropriate.</p>
<i>Technological Comparison</i>	<p>Compared to the predicate device Arthrex Intramedullary Nails (K230257), the Arthrex Anti-Rotation Screw, 5.0 x 115 mm is identical in design, diameter, fundamental scientific technology, materials, packaging, sterility, shelf-life, and MRI labeling. The only difference is related to the length. The Arthrex Anti-Rotation Screw, 5.0 x 115 mm will introduce a longer length (115 mm) than the predicate device Arthrex Intramedullary Nails (K230257).</p>
<i>Conclusion</i>	<p>The Arthrex Anti-Rotation Screw, 5.0 x 115 mm is substantially equivalent to the predicate devices cleared under K230257 in which basic design features and intended use are the same. Any differences between the Arthrex Anti-Rotation Screw, 5.0 x 115 mm and the predicate device is 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 devices.</p>