July 17, 2023

Arthrex, Inc.
Stacy Valdez
Senior Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K230257
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: June 13, 2023
Received: June 15, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Thomas Mcnamara -S

Digitally signed by Thomas Mcnamara -S
Date: 2023.07.17 14:14:03 -04'00'

For: Farzana Sharmin, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230257

Device Name
Arthrex Intramedullary Nails

Indications for Use *(Describe)*
The antegrade femoral nail is intended for use in intramedullary fixation of fractures of the femur to include the following: Open and closed femoral fractures, Pseudoarthrosis and correction osteotomy, Pathologic fractures, impending pathologic fractures and tumor resections, Supracondylar fractures, including those with severe comminution and intra articular extension, Ipsilateral femur fractures, bone lengthening, fractures proximal to a total knee arthroplasty or prosthesis, fractures distal to a hip joint, nonunions and malunions, and fractures resulting from osteoporosis.

The retrograde femoral nail is intended for use in intramedullary fixation of fractures of the femur to include the following: Open and closed femoral fractures, Pseudoarthrosis and correction osteotomy, Pathologic fractures, impending pathologic fractures and tumor resections, Supracondylar fractures, including those with severe comminution and intra articular extension, Ipsilateral femur fractures, bone lengthening, fractures proximal to a total knee arthroplasty or prosthesis, fractures distal to a hip joint, nonunions and malunions, and fractures resulting from osteoporosis.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230257

Device Name
Arthrex Intramedullary Nails

Indications for Use *(Describe)*
The tibial nail system is intended to provide temporary stabilization of various types of fractures, malunions, and nonunions of the tibia. The tibial nail system is indicated for long bone fracture fixation of tibial fractures, which may include the following: traverse, oblique, spiral, segmental and comminuted fractures; fractures with bone loss and bone transport; open and closed fractures, pathologic fractures; corrective osteotomies; pseudarthrosis of the tibial shaft; nonunions, malunions, metaphyseal and epiphyseal 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230257

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)

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510(k) Summary

Date Prepared	07/14/2023
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Stacy Valdez Senior Regulatory Affairs Specialist 1-239-643-5553, ext. 72010 Stacy.valdez@arthrex.com
Name of Device	Arthrex Intramedullary 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	K133081: AOS Intramedullary Nail
Additional Predicate Device(s)	K202099: AOS Galileo Trochanteric Nail System K141228: AOS Antegrade Femoral Nail System K132005: AOS Retrograde Femoral Nail System K130625: AOS 12 mm and 13 mm Tibial Nails K123569: AOS Antegrade Femoral Nail System K103533: AOS ES Trochanteric Nail K070444: AOS Tibial Nail K021008: Advanced Orthopaedic Solutions Trochanteric Nail
Reference Device(s)	K222267: Arthrex 2.4 mm Volar Distal Radius Plate System K221031: Arthrex DualCompression Hindfoot Fusion Nail System K213837: Arthrex Ankle Fracture System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Intramedullary Nails.
Device Description	The Arthrex Intramedullary Nails are comprised of Femoral, Tibial, and Trochanteric Nail Systems. The proposed Arthrex Femoral Nail System is comprised of femoral nails (antegrade, retrograde, supracondylar retrograde), proximal and distal locking screws, end caps, spacer, and washers. All retrograde nails are threaded on the distal end to accept an end cap. The proximal and distal locking screws are comprised of fully threaded, cancellous or cortical screws and partially threaded cancellous screws. The Arthrex Femoral Nail System is manufactured from Titanium Alloy (Ti-6AL-4V ELI conforming to ASTM F136). The Arthrex Femoral Nail System is sold sterile and is single-use. The proposed Arthrex Tibial Nail System is comprised of tibial nails, proximal and distal locking screws, end caps, and spacer of varying lengths and diameters. The tibial nail contains slots to accept the locking screws. The proximal and distal locking and blocking screws are comprised of fully threaded, cortical screws and partially threaded cannulated cancellous screws. The end caps are designed to prevent bony in-growth in the distal portion of the nail implant. The spacer is provided for proximal locking. The Arthrex Tibial Nail System is manufactured from Titanium Alloy (Ti-6AL-4V ELI confirming to ASTM F136). The Arthrex Tibial Nail System is sold sterile and single-use.

	The proposed Arthrex Trochanteric Nail System is comprised of trochanteric nails (short, ES [Extended Short], and long), proximal and distal locking screws, and end caps. The trochanteric nails have slots to accept distal and proximal screws. The proximal end of the nail is threaded to accept an end cap. The Arthrex Trochanteric Nail System (nails, screws, and end caps) is manufactured from Titanium Alloy (Ti-6AL-4V ELI conforming to ASTM F136) and Stainless Steel (316LVM conforming to ASTM F138).
Indications for Use	The antegrade femoral nail is intended for use in intramedullary fixation of fractures of the femur to include the following: Open and closed femoral fractures, Pseudoarthrosis and correction osteotomy, Pathologic fractures, impending pathologic fractures and tumor resections, Supracondylar fractures, including those with severe comminution and intra articular extension, Ipsilateral femur fractures, bone lengthening, fractures proximal to a total knee arthroplasty or prosthesis, fractures distal to a hip joint, nonunions and malunions, and fractures resulting from osteoporosis. The retrograde femoral nail is intended for use in intramedullary fixation of fractures of the femur to include the following: Open and closed femoral fractures, Pseudoarthrosis and correction osteotomy, Pathologic fractures, impending pathologic fractures and tumor resections, Supracondylar fractures, including those with severe comminution and intra articular extension, Ipsilateral femur fractures, bone lengthening, fractures proximal to a total knee arthroplasty or prosthesis, fractures distal to a hip joint, nonunions and malunions, and fractures resulting from osteoporosis. The tibial nail system intended to provide temporary stabilization of various types of fractures, malunions, and nonunions of the tibia. The tibial nail system is indicated for long bone fracture fixation of tibial fractures, which may include the following: traverse, oblique, spiral, segmental and comminuted fractures; fractures with bone loss and bone transport; open and closed fractures, pathologic fractures; corrective osteotomies; pseudarthrosis of the tibial shaft; nonunions, malunions, metaphyseal and epiphyseal fractures. 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.
Performance Data	Arthrex conducted packaging validation and 5-year accelerated aging

	shelf-life testing to demonstrate that the 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 Intramedullary Nails 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 within the Arthrex Tibial Nail System meet pyrogen limit specifications.
Technological Comparison	The Arthrex Femoral Nail System was previously cleared as the AOS Femoral Nail System under K141228, K133081, K132005, and K123569. The Arthrex Femoral Nail System is substantially equivalent to the predicate devices cleared under K133081 in which the intended use, fundamental scientific technology, design, material, sterility, and shelf-life are identical. The Arthrex Tibial Nail System was previously cleared as the AOS Tibial Nail System under K070444, K130625, and K133081. The Arthrex Tibial Nail System is substantially equivalent to the predicate devices cleared under K133081 in which the intended use, fundamental scientific technology, design, material, sterility, and shelf-life are identical. The Arthrex Trochanteric Nail System was previously cleared as the AOS Trochanteric Nail System under K012190, K021008, K070444, K103533, K120148, K123569, K133081, and K202099. The Arthrex Trochanteric Nail System is substantially equivalent to the predicate devices cleared under K133081 in which the intended use, fundamental scientific technology, design, material, sterility, and shelf-life are identical. The Arthrex Femoral Nail System (sterile nails) are offered larger in proximal diameter and shorter/longer lengths than the primary predicate AOS Intramedullary Nail, K133081. The larger proximal diameter and shorter/longer lengths of the sterile nails were originally cleared as non-sterile under additional predicate devices AOS Antegrade Femoral Nail System, K123569 and AOS Retrograde Femoral Nail System, K132005.

	The Arthrex Trochanteric Nail System (sterile nails) are longer in length than the primary predicate AOS Intramedullary Nail, K133081. The longer length of the sterile nails were originally cleared as non-sterile under additional predicate device AOS Galileo Trochanteric Nail System, K202099. The Arthrex Tibial Nail System (sterile screws) are offered in shorter and longer lengths than the primary predicate AOS Intramedullary Nail, K133081. The shorter and longer lengths of the sterile screws were originally cleared as non-sterile under additional predicate device AOS Tibial Nail, K070444. The Arthrex Trochanteric Nail System (sterile screws) are offered in shorter and longer lengths than the primary predicate AOS Intramedullary Nail, K133081. The shorter and longer lengths of the sterile screws were originally cleared as non-sterile under additional predicate device Advanced Orthopaedic Solutions Trochanteric Nail, K021008. The Arthrex Tibial Nail System (sterile end cap) is a larger size than the primary predicate AOS Intramedullary Nail, K130081. However, the larger size was originally cleared as non-sterile under additional predicate device AOS Antegrade Femoral Nail System, K123569. The sterile packaging for the Arthrex Intramedullary Nails is changing to a double nylon/nylon pouch (for the nails), a double PETG blister tray with Tyvek lidding (for the screws, end caps, and spacer), and a double PETG blister tray with Tyvek lidding or double poly/Tyvek pouch (for the washers). These are existing packaging configurations cleared under reference device Arthrex 2.4 mm Volar Distal Radius Plate System, K222267 and Arthrex Ankle Fracture System, K213837. The Arthrex Intramedullary Nails were evaluated for MR Conditional labeling. The primary predicate AOS Intramedullary Nail, K133081 was not evaluated for MR Safety. The Arthrex Intramedullary Nails is substantially equivalent to the predicate devices cleared under K133081, with minor modifications with no change to the intended use, design, or function. Any differences between the Arthrex Intramedullary Nails and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.
Conclusion	The Arthrex Intramedullary Nails are substantially equivalent to the predicate devices cleared under K133081 in which the basic design features and intended use are the same. Any differences between the Arthrex Intramedullary Nails and the predicate devices 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 devices.