December 20, 2022

Arthrex Inc.
Rebecca Homan
Team Lead, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K221031
Trade/Device Name: Arthrex DualCompression Hindfoot Fusion Nail Implant System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 30, 2022
Received: November 30, 2022

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 (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,

Victoria A. Lilling -S

Digitally signed by Victoria A. Lilling -S
Date: 2022.12.20 15:31:51 -05'00'

Victoria Lilling, M.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)*

K221031

Device Name
Arthrex DualCompression Hindfoot Fusion Nail Implant System

Indications for Use *(Describe)*
The Arthrex DualCompression Hindfoot Fusion Nail Implant System is intended to facilitate tibiotalocalcaneal arthrodesis to treat severe foot/ankle deformity, arthritis, instability, and skeletal defects after tumor resection. These include neuro-osteoarthropathy (Charcot's Foot), avascular necrosis of the talus, failed joint replacement, failed ankle fusion, distal tibia fracture non-unions, osteoarthritis, rheumatoid arthritis, and pseudoarthrosis.

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

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| ***Date Prepared*** | December 19, 2022 |
| ***Submitter*** | Arthrex Inc.<br>1370 Creekside Boulevard<br>Naples, FL 34108-1945 |
| ***Contact Person*** | Rebecca R. Homan<br>Team Lead, Regulatory Affairs – Product Development<br>1-239-643-5553, ext. 73429<br>rebecca.homan@arthrex.com |
| ***Name of Device*** | Arthrex DualCompression Hindfoot Fusion Nail Implant System |
| ***Common Name*** | Rod, Fixation, Intramedullary And Accessories |
| ***Product Code*** | HSB |
| ***Classification Name*** | 21 CFR 888.3020: Intramedullary fixation rod |
| ***Regulatory Class*** | II |
| ***Predicate Device*** | K090857: Wright Medical VALOR Ankle Fusion Nail System |
| ***Reference Device*** | K142602: Wright Medical VALOR Hindfoot Fusion Nail System<br>K171376: Medshape Solutions DynaNail TTC Fusion System<br>K113828: Medshape Solutions DynaNail Ankle Arthrodesis Nail |
| ***Purpose of Submission*** | This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex DualCompression Hindfoot Fusion Nail Implant System. |
| ***Device Description*** | The Arthrex DualCompression Hindfoot Fusion Nail Implant System is comprised of the Arthrex DualCompression Hindfoot Fusion Nails, Interlocking Screws, Cable and End Caps. The Arthrex DualCompression Hindfoot Nail is available in 10.5, 11.5 and 12.5 mm diameters and lengths of 180, 210, 240 and 300 mm. The Interlocking Screws are fully threaded, headed or headless, self-tapping, solid, low profile screws. The screw family is 5.0 mm in diameter and ranges from 20 mm to 120 mm in length (in 2 or 5 mm increments). The End Caps are designed to prevent bone in growth in the distal portion of the Nail implant for ease of removal. The end cap family ranges from 1 to 11 mm in length for various countersinking depths.<br><br>The Arthrex DualCompression Hindfoot Fusion Nails are manufactured from Titanium Alloy (Ti-6AL-4V conforming to ASTM F136), Superelastic Nitinol (conforming to ASTM F2063) and Polyetheretherketone (PEEK)(conforming to ASTM F2026). The Arthrex DualCompression Hindfoot Nail is sold sterile and is single-use. The Interlocking Screws and End Caps are manufactured from Titanium Alloy (Ti-6AL-4V conforming to ASTM F136). The Interlocking Screws and End Caps are sold non-sterile and are single-use. |
| ***Indications for Use*** | The Arthrex DualCompression Hindfoot Fusion Nail Implant System is intended to facilitate tibiotalocalcaneal arthrodesis to treat severe foot/ankle deformity, arthritis, instability, and skeletal defects after tumor resection. These include neuro-osteoarthropathy (Charcot's Foot), avascular necrosis of the talus, failed joint replacement, failed ankle fusion, distal tibia fracture non-unions, osteoarthritis, rheumatoid arthritis, and pseudoarthrosis. |
| ***Performance Data*** | Static four-point bend, static torque, dynamic compression bending fatigue, fatigue strength, static and dynamic 3-point bend (ASTM F1264-16e1), axial pull-out, maximum torque, and breaking angle (ASTM F543-17) testing was conducted to demonstrate that the Arthrex DualCompression Hindfoot Fusion Nail Implant System performs equivalent to the predicate devices cleared under K090857. |

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| | Corrosion resistance (ASTM F2129), fretting corrosion (ASTM F1875, ATM F897) and bend and free recovery (ASTM F2082/F2082M) testing was conducted on the Arthrex DualCompression Hindfoot Fusion Nail Implant System. An in-vitro fretting corrosion (ASTM F1875) and ion release (ASTM F3306) study was conducted on the Arthrex DualCompression Hindfoot Fusion Nail Implant System.<br><br>Arthrex preformed engineering analyses to conclude that the insertion torque, failure torque, driving torque and removal torque values of the Arthrex DualCompression Hindfoot Fusion Nail Implant System were acceptable.<br><br>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*.<br><br>Bacterial Endotoxins Test (BET) was performed on the Arthrex DualCompression Hindfoot Fusion Nail Implant System 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 DualCompression Hindfoot Fusion Nail Implant System meet pyrogen limit specifications.<br><br>Cytotoxicity, Sensitization, Irritation, Genotoxicity, Systemic Toxicity, Subchronic/Subacute Toxicity, Implantation and Material Characterization testing was conducted on the devices within the Arthrex DualCompression Hindfoot Fusion Nail Implant System in accordance with ISO 10993-1:2018.<br><br>Assessment of physical product attributes including product, design, size, and materials has determined that the Arthrex DualCompression Hindfoot Fusion Nail Implant System does not introduce additional risks or concerns regarding sterilization and shelf-life. |
| ***Technological Comparison*** | The Arthrex DualCompression Hindfoot Fusion Nail Implant System is substantially equivalent to the primary predicate devices cleared under K090857; and reference devices cleared under K142602, K171376 and K113828 in which the basic design features, intended use and fundamental scientific technology are identical.<br><br>The Arthrex DualCompression Hindfoot Fusion Nail Implant System is comprised of the Arthrex DualCompression Hindfoot Fusion Nails, Interlocking Screws, Cable and End Caps.<br><br>• The Arthrex DualCompression Hindfoot Nail is available in 10.5, 11.5 and 12.5 mm proximal diameters (with a 12.5 mm distal diameter) and lengths of 180, 210, 240 and 300 mm. The Arthrex DualCompression Hindfoot Fusion Nails are manufactured from |

Titanium Alloy (Ti-6AL-4V conforming to ASTM F136), Superelastic Nitinol (conforming to ASTM F2063) and Polyetheretherketone (PEEK)(conforming to ASTM F2026). The Arthrex DualCompression Hindfoot Fusion Nails are sold sterile and are single-use.

- The Interlocking Screws are fully threaded, headed or headless self-tapping solid low profile screws. The headed and headless screw family is 5.0 mm in diameter and ranges from 20 mm to 120 mm in length (in 2 or 5 mm increments). The End Cap family ranges from 1 to 11 mm in length for various countersinking depths The Interlocking Screws and End Caps are manufactured from Titanium Alloy (Ti-6AL-4V conforming to ASTM F136). The Interlocking Screws and End Caps are sold non-sterile and are single-use.

- The Arthrex DualCompression Hindfoot Fusion Cable is manufactured from Stainless Steel (conforming to ASTM F138). The Arthrex DualCompression Hindfoot Fusion Cable is sold sterile and is single-use.

The primary predicate device Wright Medical VALOR Ankle Fusion Nail System, K930834 is comprised of the Wright Medical VALOR Ankle Fusion Nails and screws. The nails were cleared in 10.0 and 11.5 proximal diameters (with a 12.5 mm distal diameter) and lengths of 150, 200 and 250 mm. The screws were cleared with a Ø5.0 mm diameter and lengths ranging from 20 mm to 100 mm. The nails and screws are manufactured from Titanium Alloy. The nails and screws are single-use.

The reference device Wright Medical VALOR Hindfoot Fusion Nail System, K142602 is comprised of the Wright Medical VALOR Hindfoot Fusion Nails and screws. The nails were cleared in 10.0 and 11.5 proximal diameters (with a 12.0 mm distal diameter) and length of 300 mm. The screws were cleared with a Ø5.0 mm diameter and lengths ranging from 20 mm to 120 mm. The nails and screws are manufactured from Titanium Alloy. The nails and screws are single-use.

The reference device Medshape Solutions DynaNail TTC Fusion System, K171376 is comprised of the Medshape Solutions DynaNail TTC Fusion Nails and screws. The nails were cleared in 10, 11 and 12 mm proximal diameters (with a 12.5 mm distal diameter) and length of 180, 220, 260, and 300 mm. The headed and headless screws were cleared with a Ø5.0 mm diameter and lengths ranging from 20 mm to 110 mm. The nails are manufactured from Titanium Alloy and Nitinol. The screws are manufactured from Titanium Alloy. The nails and screws are single-use.

The reference device Medshape Solutions DynaNail Ankle Arthrodesis Nail, K113828 is comprised of the Medshape Solutions DynaNail Ankle Arthrodesis Nails and screws. The nails were cleared in 10, 11 and 12 mm proximal diameters (with a 12.5 mm distal diameter) and length of 180, 220, 260, and 300 mm. The headed and headless screws were cleared with a Ø5.0 mm diameter and lengths ranging from 20 mm to 110 mm. The nails are manufactured from Titanium Alloy and Nitinol. The screws are manufactured from Titanium Alloy. The nails and screws are single-use.

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| | The Arthrex DualCompression Hindfoot Fusion Nail Implant System was evaluated for MR Conditional labeling, while the MRI Safety of primary predicate devices cleared under K090857 and reference devices cleared under K142602, K171376 and K113828 is unknown.<br><br>The Arthrex DualCompression Hindfoot Fusion Nail Implant System is substantially equivalent to the primary predicate devices cleared under K090857; and reference devices cleared under K142602, K171376 and K113828, with minor dimensional modifications with no change to intended use or function. Any differences between the Arthrex DualCompression Hindfoot Fusion Nail Implant System and the predicate devices are considered minor and do not raise different questions of safety or effectiveness. |
| ***Conclusion*** | The Arthrex DualCompression Hindfoot Fusion Nail Implant System is substantially equivalent to the predicate devices cleared under K090857, K142602, K171376 and K113828; in which the basic design features and intended use are the same. Any differences between the Arthrex DualCompression Hindfoot Fusion Nail Implant System and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.<br><br>The submitted mechanical testing data demonstrates that the static four-point bend, static torque, dynamic compression bending fatigue, fatigue strength, static and dynamic 3-point bend and axial pull-out strength of the Arthrex DualCompression Hindfoot Fusion Nail Implant System is substantially equivalent to that of the predicate devices for the desired indications.<br><br>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. |