October 29, 2026

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

Re: K263602
Trade/Device Name: Arthrex Plates, Screws and Pins, and Washers
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC, HTN, MBI, JDR
Dated: September 30, 2026
Received: September 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma 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.	K263602	?

Please provide the device trade name(s). ?

Arthrex Plates, Screws and Pins, and Washers

Please provide your Indications for Use below. ?

The Arthrex Distal Radius System is intended for fixation of fractures, fusions, osteotomies, and non-unions of the radius, ulna, olecranon, metacarpal, metatarsal, and malleolus.

The Arthrex Modified Osteotomy System, designed for Opening Wedge Distal Tibial, Distal Femoral, Proximal Tibial osteotomies, and High Tibial Closing Osteotomies, is used in conjunction with bone screws to provide fixation following surgery. Specifically for use in treatment of non-union, malunion, and fractures of proximal tibia, distal femur, and distal tibia including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures. Specially sloped plates can be used in cases when a tibial slope adjustment is needed. This system consists of plates and screws which join together to correct abnormalities or trauma related injuries. It is intended to be used with adequate post-operative immobilization.

The Arthrex Humeral Fracture Plates and Screws are intended to provide internal fixation of proximal fractures of the humerus.

The Arthrex Distal Extremity Plate System is intended for use in stabilization of fresh fractures, revision procedures, osteotomies, joint fusion and reconstruction of small bones and bone fragments of the hand/ wrist, foot/ankle, and osteopenic bone.

The Arthrex Compression Plates are intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle, foot, hand and wrist, such as opening wedge osteotomies of Hallux Valgus.

The Arthrex Low Profile Plate and Screw System is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle, foot, hand, and wrist, such as opening wedge osteotomies of Hallux Valgus.

The Arthrex TightRope™ Syndesmosis Device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the Arthrex TightRope™ Syndesmosis Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

The Arthrex Minimally Invasive Ankle Fusion Plate is intended to be used for fixation of bone fractures and fusions in the foot and ankle. The Arthrex Minimally Invasive Ankle Fusion Plate is to be used with the Arthrex Low Profile Screws.

The Arthrex Ankle Fusion Plating System is intended to be used for internal bone fixation for bone fractures,

fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, and fibula.

The Arthrex Fracture Plates are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, fibula.

The Arthrex Low Profile Screws (2.0-2.4mm solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile, Small Fragment Plates, and Distal Extremity Plates.

The Arthrex Low Profile Screws (2.0-3.0mm cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist.

The Arthrex Low Profile Screws (2.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Humeral Fracture Plates, and Osteotomy Plates.

The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula.

The Arthrex Interference Screws are intended to be used for fixation of tissue including ligament or tendon to bone and bone tendon bone. Interference fixation with PEEK, Titanium, or Bioabsorbable Polymer Interference Screws is appropriate for surgeries of the knee, shoulder, elbow, ankle, foot, and hand/wrist where the sizes offered are patient appropriate. Specifically;

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/ wrist

The Arthrex Fracture Plates are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, fibula.

The Arthrex Low Profile Screws (2.0-2.4mm solid) are intended to be used as stand-alone bone screws, or in a plate screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile, Small Fragment Plates, and Distal Extremity Plates.

The Arthrex Low Profile Screws (2.0-3.0mm cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist.

The Arthrex Low Profile Screws {2.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile, Small Fragment Plates, Fracture Plates, distal Extremity Plates, Humeral Fracture Plates, and Osteotomy Plates.

The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula.

The Arthrex Low Profile Screws (2.0-3.0mm solid) are intended to be used as stand-alone bone screws, or in a plate screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile and Small Fragment
Plates.

The Arthrex Low Profile Screws (2.0-3.0mm cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist.

The Arthrex Low Profile Screws (3.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile and Small Fragment Plates, Humeral Fracture Plates, and Osteotomy Plates.

The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula.

The Arthrex Low Profile Screws (3.0 mm, solid) are intended to be used as stand-alone bone screws, or in a plate screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Mesh Plates.

The Arthrex KreuLock Compression Screws (2.0-3.0 mm solid) are intended to be used in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Distal Extremity Plates, Mesh Plates (2.7-3.0) and Distal Radius Plates.

The Arthrex KreuLock Compression Screws (3.5 mm and larger, solid) are intended to be used in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, femur and fibula.

When used with a plate, the screws may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Distal Radius Plates, Humeral Fracture Plates, Osteotomy Plates, and Ankle Fusion Plates.

The Arthrex Pilon Fusion Plates are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, tibia, and calcaneous.

The Arthrex Low Profile Screws (3.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Humeral Fracture Plates and Osteotomy Plates.

The Arthrex Low Profile Screws (2.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Humeral Fracture Plates, and Osteotomy Plates.

The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula.

The Arthrex Compression FT pins (1.9 mm) are intended for small bone fracture and osteotomy fixation in the hand, wrist, foot, ankle and knee.

The Arthrex Compression FT pins (2.4 mm) are intended for fixation of small bone fragments, such as apical fragments, osteochondral fragments and cancellous fragments. Specific applications include the following:

- Osteochondral fragments (talar vault, femoral condyle)
- Apical fragments (radial head, patellar rim, navicular, metacarpal/metatarsal)
- Cancellous fragments (talus)
- Carpal, metacarpal, and small hand bone
- Tarsal and metatarsals
- Phalanges
- Intra-articular fractures
- Ankle
- Proximal and distal humerus
- Proximal and distal radius
- Proximal and distal ulna
- Osteochondral fixation and fractures
- Osteochondritis Dissecans
- Fixation of fractures and osteotomies about the knee
- Reconstructive surgeries of the foot
- Malleolar fixation
- Oblique fractures of the fibula

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)

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510(k) Summary

Date Prepared	10/29/2026
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Rebecca R. Homan Title: Manager, Regulatory Affairs Phone: 1-239-643-5553, ext. 73429 Email: Rebecca.homan@arthrex.com
Trade Name	Arthrex Plates, Screws and Pins, and Washers
Common Name	Plates, Screws and Pins, and Washers
Product Code	HRS (Primary), HWC, HTN, MBI, JDR
Classification Name	21 CFR 888.3030 single/multiple component metallic bone fixation appliances and accessories (Primary) 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Primary Predicate Device	K143749 Arthrex Distal Radius System
Additional Predicate Devices	K150456 Arthrex Plates, Screws, and Staples K052614 Arthrex Low Profile Plate and Screw System K111253 Arthrex Distal Extremity Plate System K043248 Arthrex TightRope™ Syndesmosis Device K190953 Arthrex Minimally Invasive Ankle Fusion Plate K141735 Arthrex Ankle Fusion Plating System K123241 Arthrex Fracture Plates and Screws K062466 Arthrex Interference Screw K141478 Arthrex Fracture Plates and Screws K143614 Arthrex Low Profile Screws K170547 Arthrex Web Plate System K201132 Arthrex Compression FT Screws K203294 Arthrex Primary Pilon Fusion System K213837 Arthrex Ankle Fracture System K220839 Arthrex Compression FT Pins
Reference Devices	K251145 Arthrex PushLock Suture Anchors K253931 Arthrex Bioabsorbable PushLock Suture Anchors
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain FDA clearance for the subject Arthrex Plates, Screws

	and Pins, and Washers sterilized using the Arthrex X-ray sterilization process.
Device Description	The Arthrex Distal Radius System is a family of implantable titanium plates and screws contoured and in left and right configurations, ranging in length from 25 mm to 166 mm and feature both locking and non-locking holes. The screws are solid, fully or partially threaded, and may be locking or non-locking. The screws are 2.4 mm to 3.5 mm in diameter and 8 mm to 34 mm in length. The plates and screws are offered sterile and non-sterile and are single-use. The Arthrex Plates, Screws, and Staples is a family of plates, screws, and staples manufactured from stainless steel or titanium that will be offered as sterile or non-sterile devices in various sizes for use in orthopedic surgery for single-use. The low profile plates are L-shaped, opening wedge style and closing wedge flat style, titanium plates with 3.2 mm holes for screw fixation. The predicate plates range in length from 21.5 to 27.5 mm and are 0.5 mm thick. The plates and screws are offered sterile and non-sterile and are single-use. The Arthrex Distal Extremity Plate System is comprised of a variety of flat and pre-contoured plate geometries. The plates are manufactured from titanium and feature both locking and non-locking holes. The screw ranges from 2.0 mm to 4.0 mm in diameter and in length from 8 mm to 80 mm. The screws are solid and may be either locking or non-locking. The plates and screws are offered sterile and non-sterile and are single-use. The Arthrex TightRope™ Syndesmosis Device is designed as two differently sized metal buttons, both stainless steel or both titanium, and FiberWire™ suture. The buttons are pre-threaded with FiberWire suture, looped twice through the buttonholes. A long straight needle with pull-through FiberWire suture is also looped through the leading button. The Arthrex Buttress Plate is a metal plate manufactured from either titanium alloy or stainless steel for use with the Arthrex TightRope Syndesmosis Device. The round buttons of the TightRope Device seat flush within the Buttress Plate creating a longer, button construct. The TightRope Device is

offered sterile and is single-use. The Buttress Plates are offered sterile and non-sterile and are single-use.

The Arthrex Minimally Invasive Ankle Fusion Plate is a Titanium bone fixation device intended to be permanently implanted. The implant has 3-holes that accept screws, a tapered proximal tip, and an anatomically contoured distal portion. The plate is designed to be fixated to the anterior-medial aspect of the distal tibia with 4.5 mm locking or nonlocking screws in order to facilitate tibiotalar (TT) fusions. The plate is offered sterile and non-sterile and is single-use.

The Arthrex Ankle Fusion Plating System is a family of implantable titanium plates and screws intended to be used for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions. The subject plates are contoured and may be available in left and right configurations, ranging in length from 91.9 mm to 133.6 mm. The accompanying screws are solid or cannulated, fully or partially threaded, and may be locking or non-locking. The plates and screws are offered sterile and non-sterile and are single-use.

The Arthrex Fracture Plates are a family of flat and contoured plate geometries. The plates are comprised of stainless steel or titanium, and come in a variety of configurations. The screws, which are used with the Arthrex Ankle Fracture Plates, include the solid locking and non-locking Low Profile Screws. The Low Profile Screws are comprised of Stainless Steel or Titanium and range in diameter from 2.0 mm to 6.7 mm and from 8 mm to 120 mm in length. The washers are round, and flat, comprised of either titanium or steel. The washers are intended to be used as an adjunct to the Arthrex Low Profile Screws for internal bone fixation of bone fractures, fusions, osteotomies. The washers range in size from 6.0 – 13.0 mm in diameter and 1.0 – 1.6 mm in width. The plates and screws are offered sterile and non-sterile and are single-use.

The Arthrex Interference Screws have a diameter of 5 mm to 11 mm and were 15 to 50 mm in length. The interference screw products were threaded, or partially threaded, and

cannulated or non-cannulated. Many of the models were delivered in a sheath or had a washer. The screws are manufactured from titanium. The screws are offered sterile and are single-use.

The Arthrex Fracture Plates and Screws are a family of titanium and stainless steel plates and screws. The plates are flat and contoured, ranging from 50 mm to 244 mm in length. The accompanying screws are 2.0 mm to 6.7 mm in diameter. The screws are offered sterile and non-sterile and are single-use.

The Arthrex Low Profile Screws are titanium or stainless steel, fully or partially threaded, solid or cannulated, self-tapping, headed screws. The screws range from 2.0 mm to 4.0 mm in diameter and in length from 8 mm to 80 mm. The screws are offered sterile and non-sterile and are single-use.

The Arthrex Web Plate System is a family of plates and screws made from stainless steel and titanium. The system is comprised of the Arthrex Web Plates and accompanying Arthrex Low Profile Screws. The plates in long and short versions are offered sterile and non-sterile. The accompanying low profile screws, 2.7 mm and 3.0 mm screws with lengths ranging from 10 mm to 50 mm. The screws are offered sterile and non-sterile and are single-use.

The Arthrex Compression FT Screws are offered in five diameters, 2.8 mm, 3.8 mm, 4.6 mm, 5.0 mm and 7.0 mm. and range in lengths from 8 mm to 140 mm. The screws are manufactured from Titanium, conforming to ASTM Standards F136 and F1472. The screws are available in two options: sterile (Gamma), single-use and non-sterile, single-use.

The Arthrex Primary Pilon Fusion System consists of a series of plates and screws of varying lengths and orientations for versatile treatment of distal tibia fractures that require not only fracture reduction but a primary ankle arthrodesis. The Arthrex Pilon Fusion Plates consist of both anterolateral and posterior plates in left and right configurations that are anatomically contoured to provide fixation in the talus. The

	plates are attached to bone with 3.5 mm nonlocking Arthrex Low Profile Screws ranging in length from 10 mm to 60 mm in length. The plates and screws are manufactured from Titanium alloy conforming to ASTM F136 and will be sold as sterile, single-use and non-sterile, single-use. The Arthrex Ankle Fracture System consists of a series of plates and screws of varying lengths and orientations for versatile treatment of distal tibia fractures. The Ankle Fracture System plates consist of posterior and vertical plates that are anatomically contoured to provide fixation in the talus and may be available in left and right configurations. Each plate provides locking screw fixation. The Arthrex Low Profile Screws are a family of fully threaded, solid, non-locking or locking screws; and partially threaded, cannulated, and non-locking screws. The plates and screws are manufactured from titanium alloy. The plates and screws are sold sterile (gamma sterilized) and non-sterile and are single-use. The Arthrex Compression FT Pins are a family of solid, fully threaded, self-tapping pins with a tapering head with and without a snap-off function designed to provide fixation of fractures, osteotomies and arthrodesis. The pins are offered in two diameters: 1.9 mm and 2.4 mm, and range in lengths from 10 mm to 50 mm. The pins are manufactured from Titanium Alloy, conforming to ASTM F136. The pins are offered sterile and non-sterile and are single-use.
Indications for Use	The Arthrex Distal Radius System is intended for fixation of fractures, fusions, osteotomies, and non-unions of the radius, ulna, olecranon, metacarpal, metatarsal, and malleolus. The Arthrex Modified Osteotomy System, designed for Opening Wedge Distal Tibial, Distal Femoral, Proximal Tibial osteotomies, and High Tibial Closing Osteotomies, is used in conjunction with bone screws to provide fixation following surgery. Specifically for use in treatment of non-union, malunion, and fractures of proximal tibia, distal femur, and distal tibia including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated

	shaft fractures. Specially sloped plates can be used in cases when a tibial slope adjustment is needed. This system consists of plates and screws which join together to correct abnormalities or trauma related injuries. It is intended to be used with adequate post-operative immobilization. The Arthrex Humeral Fracture Plates and Screws are intended to provide internal fixation of proximal fractures of the humerus. The Arthrex Distal Extremity Plate System is intended for use in stabilization of fresh fractures, revision procedures, osteotomies, joint fusion and reconstruction of small bones and bone fragments of the hand/wrist, foot/ankle, and osteopenic bone. The Arthrex Compression Plates are intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle, foot, hand and wrist, such as opening wedge osteotomies of Hallux Valgus. The Arthrex Low Profile Plate and Screw System is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle, foot, hand, and wrist, such as opening wedge osteotomies of Hallux Valgus. The Arthrex TightRope™ Syndesmosis Device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically, the Arthrex TightRope™ Syndesmosis Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures. The Arthrex Minimally Invasive Ankle Fusion Plate is intended to be used for fixation of bone fractures and fusions in the foot and ankle. The Arthrex Minimally Invasive

	Ankle Fusion Plate is to be used with the Arthrex Low Profile Screws. The Arthrex Ankle Fusion Plating System is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, and fibula. The Arthrex Fracture Plates are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, fibula. The Arthrex Low Profile Screws (2.0-2.4mm solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile, Small Fragment Plates, and Distal Extremity Plates. The Arthrex Low Profile Screws (2.0-3.0mm cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist. The Arthrex Low Profile Screws (2.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Humeral Fracture Plates, and Osteotomy Plates. The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions,

	osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. The Arthrex Interference Screws are intended to be used for fixation of tissue including ligament or tendon to bone and bone tendon bone. Interference fixation with PEEK, Titanium, or Bioabsorbable Polymer Interference Screws is appropriate for surgeries of the knee, shoulder, elbow, ankle, foot, and hand/wrist where the sizes offered are patient appropriate. Specifically; Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, lliotibial Band Tenodesis Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/ wrist The Arthrex Fracture Plates are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist,

	clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, fibula. The Arthrex Low Profile Screws (2.0-2.4mm solid) are intended to be used as stand-alone bone screws, or in a plate screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile, Small Fragment Plates, and Distal Extremity Plates. The Arthrex Low Profile Screws (2.0-3.0mm cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist. The Arthrex Low Profile Screws {2.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile, Small Fragment Plates, Fracture Plates, distal Extremity Plates, Humeral Fracture Plates, and Osteotomy Plates. The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula. The Arthrex Low Profile Screws (2.0-3.0mm solid) are intended to be used as stand-alone bone screws, or in a plate screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile and Small Fragment Plates.

	The Arthrex Low Profile Screws (2.0-3.0mm cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist. The Arthrex Low Profile Screws (3.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile and Small Fragment Plates, Humeral Fracture Plates, and Osteotomy Plates. The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula. The Arthrex Low Profile Screws (3.0 mm, solid) are intended to be used as stand-alone bone screws, or in a plate screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Mesh Plates. The Arthrex KreuLock Compression Screws (2.0-3.0 mm solid) are intended to be used in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Distal Extremity Plates, Mesh Plates (2.7-3.0) and Distal Radius Plates. The Arthrex KreuLock Compression Screws (3.5 mm and larger, solid) are intended to be used in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia,

	calcaneus, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Distal Radius Plates, Humeral Fracture Plates, Osteotomy Plates, and Ankle Fusion Plates. The Arthrex Pilon Fusion Plates are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, tibia, and calcaneous. The Arthrex Low Profile Screws (3.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Humeral Fracture Plates and Osteotomy Plates. The Arthrex Low Profile Screws (2.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Humeral Fracture Plates, and Osteotomy Plates. The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula.

	The Arthrex Compression FT pins (1.9 mm) are intended for small bone fracture and osteotomy fixation in the hand, wrist, foot, ankle and knee. The Arthrex Compression FT pins (2.4 mm) are intended for fixation of small bone fragments, such as apical fragments, osteochondral fragments and cancellous fragments. Specific applications include the following: • Osteochondral fragments (talar vault, femoral condyle) • Apical fragments (radial head, patellar rim, navicular, metacarpal/metatarsal) • Cancellous fragments (talus) • Carpal, metacarpal, and small hand bone • Tarsal and metatarsals • Phalanges • Intra-articular fractures • Ankle • Proximal and distal humerus • Proximal and distal radius • Proximal and distal ulna • Osteochondral fixation and fractures • Osteochondritis Dissecans • Fixation of fractures and osteotomies about the knee • Reconstructive surgeries of the foot • Malleolar fixation • Oblique fractures of the fibula
Performance Data	To demonstrate product performance and safety, Arthrex has conducted packaging validations, product functionality (accelerated aging), product induced radiation, sterilization validation, biological safety evaluation and temperature study testing based on reference devices K251145 Arthrex PushLock Suture Anchors and K253931 Arthrex Bioabsorbable PushLock Suture Anchors.
Technological Comparison	Compared to the primary predicate and additional predicate devices, the Arthrex Plates, Screws and Pins, and Washers have the same basic design features, intended use, indications for use, fundamental scientific technology, materials, packaging, and sterility.

	The Arthrex Plates, Screws and Pins, and Washers to be sterilized using the Arthrex X-ray sterilization process while the primary predicate and additional predicate devices are sterilized using Gamma radiation. This is identical to the Arthrex X-ray sterilization process cleared under K251145 Arthrex PushLock Suture Anchors. The Arthrex Plates, Screws and Pins, and Washers are substantially equivalent to the primary predicate and additional predicate devices in which basic design features, intended use, indications for use, fundamental scientific technology, materials, packaging, and sterility are identical.
Conclusion	The Arthrex Plates, Screws and Pins, and Washers are substantially equivalent to the primary predicate and additional predicate devices in which the basic design features and intended use are the same. Any differences between the Arthrex Plates, Screws and Pins, and Washers and the primary predicate and additional 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.