Arthrex, Inc.
Ivette Galmez
Senior Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108

Re: K170547
Trade/Device Name: Arthrex Mesh Plate System
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
Dated: July 25, 2017
Received: July 28, 2017

Dear Ms. Galmez:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

The Arthrex Mesh Plate 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.

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)
Indications for Use

510(k) Number (if known)
K170547

Device Name
Arthrex Mesh Plate System

Indications for Use (Describe)

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.

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.

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# 2.1 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

<table>
<thead>
<tr>
<th><strong>Date Summary Prepared</strong></th>
<th>August 30, 2017</th>
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<tbody>
<tr>
<td><strong>Manufacturer/Distributor/Sponsor</strong></td>
<td>Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA</td>
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| **510(k) Contact** | Ivette Galmez  
Senior Regulatory Affairs Specialist  
Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, FL 34108-1945 USA  
Telephone: 239/643.5553, ext. 71263  
Fax: 239/598.5508  
Email: igalmez@arthrex.com |
| **Trade Name** | Arthrex Mesh Plate System |
| **Common Name** | Plate, fixation, bone |
| **Product Code - Classification Name** | HRS, HWC  
21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories, 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener |
| **Predicate Device** | K111253: Arthrex Distal Extremity Plate System  
K143614: Arthrex Low Profile Screws |
| **Reference Predicate** | K150456: Arthrex Plates, Screws, and Staples |
| **Purpose of Submission** | This 510(k) premarket notification is submitted to obtain clearance for the Arthrex Mesh Plate System, a line extension to the Arthrex Distal Extremity Plate System in K111253 and K150456. |
| **Device Description** | The *Arthrex Mesh Plate System* is a family of plates and screws made from stainless steel and titanium. The system is comprised of the Arthrex Mesh Plates and accompanying Arthrex Low Profile Screws. The proposed plates in long and short versions are offered sterile and non-sterile.  
The accompanying screws are 3.0 mm low profile screws with lengths ranging from 42 mm to 50 mm. The proposed screws are offered sterile and non-sterile. |
### Intended Use

The **Arthrex Mesh Plate** 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 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.

### Substantial Equivalence Summary

The **Arthrex Mesh Plate System** is substantially equivalent to the predicate devices, in which the scientific technology, and intended uses are the same. Any differences between the Arthrex Mesh Plate System and the predicates are considered minor and do not raise questions concerning safety and effectiveness.

Bacterial endotoxin testing was performed in accordance to USP <85>.

Mechanical testing data was performed in accordance to ASTM F 382-14 (Standard Specification and Test Method for Metallic Bone Plates).

The submitted data for the proposed Arthrex Mesh Plate System demonstrates that the bending strength and fatigue testing of the plates, and the torque and pull out testing of the accompanying screws are substantially equivalent to that of the predicate devices for the desired indications.

Based on the intended use, technological characteristics and the summary of data submitted, Arthrex, Inc. has determined that the **Arthrex Mesh Plate System** is substantially equivalent to the predicate.