Arthrex, Incorporated
Ms. Laura Medlin
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108-1945

August 12, 2015

Re: K151256
Trade/Device Name: Arthrex BioSync® Bone Wedge
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: PLF, HRS, HWC
Dated: May 14, 2015
Received: May 22, 2015

Dear Ms. Medlin:

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 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/ReportsProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Diision of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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 yours,

Mark N. Melkerson -S

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

Enclosure
2.4 INDICATIONS FOR USE

The Arthrex BioSync Bone Wedge is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies, in the ankle and foot, such as:

Cotton and Evans Wedges:
- Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
- Opening wedge of Medial Cuneiform or Cotton osteotomies
- Lateral Column Lengthening (Evans Lengthening Osteotomy of Cuneal Z Osteotomy)
- Metatarsal/Cuneiform arthrodesis

Midfoot Wedges:
- Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
- Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform arthrodesis (TMT or Lapidus)

This device is intended for use with ancillary fixation. The Arthrex BioSync Bone Wedge is not intended for use in the spine.
### 2.5510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

<table>
<thead>
<tr>
<th>Date Summary Prepared</th>
<th>August 5, 2015</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>
</tr>
<tr>
<td><strong>510(k) Contact</strong></td>
<td>Laura Medlin Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 72005 Fax: 239/598.5508 Email: <a href="mailto:Laura.Medlin@Arthrex.com">Laura.Medlin@Arthrex.com</a></td>
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<tr>
<td><strong>Trade Name</strong></td>
<td>Arthrex BioSync Bone Wedge</td>
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<tr>
<td><strong>Common Name</strong></td>
<td>Plate, fixation, bone Screw, fixation, bone</td>
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<tr>
<td><strong>Product Code, Classification Name</strong></td>
<td>PLF – Bone Wedge HRS – Plate, Fixation, Bone HWC – Screw, Fixation, Bone</td>
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<td><strong>Predicate Device</strong></td>
<td>K140531: Wright Medical Technology, Inc. BIOFOAM® Bone Wedge K141635: Arthrex iBalance® TKA System</td>
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<td><strong>Purpose of Submission</strong></td>
<td>This traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex BioSync Bone Wedge.</td>
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<td><strong>Device Description</strong></td>
<td>The Arthrex BioSync Bone Wedge is a family of pre-sized implantable titanium porous metal wedges intended to be used for angular correction of small bones in the ankle and foot. It is offered with varying widths and thicknesses to accommodate a variety of small bone applications.</td>
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<tr>
<td><strong>Intended Use</strong></td>
<td>The Arthrex BioSync Bone Wedge is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot, such as: Cotton and Evans Wedges:  - Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus  - Opening wedge of Medial Cuneiform or Cotton osteotomies  - Lateral Column Lengthening (Evans Lengthening Osteotomy of Calcaneal Z Osteotomy)  - Metatarsal/Cuneiform arthrodesis Midfoot Wedges:  - Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus  - Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform arthrodesis (TMT or Lapidus) This device is intended for use with ancillary fixation. The Arthrex BioSync Bone Wedge is not intended for use in the spine.</td>
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| **Substantial Equivalence Summary** | The Arthrex BioSync Bone Wedge is substantially equivalent to the predicate devices, in which the basic design features and intended uses are the same. Any differences between the Arthrex BioSync Bone Wedge and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The submitted mechanical testing data, inclusive of static compression, dynamic compression, and expulsion testing, demonstrates that the wedge is substantially
equivalent to that of the predicate devices. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the Arthrex BioSync Bone Wedge is substantially equivalent to currently marketed predicate devices.