DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 12, 2015

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

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" (21CFR 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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151256

Device Name
Arthrex BioSync® Bone Wedge

Indications for Use *(Describe)*
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/Cuneifrom 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.

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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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2.5 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	August 5, 2015
Manufacturer/ Distributor/ Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	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: Laura.Medlin@Arthrex.com
Trade Name	***Arthrex BioSync Bone Wedge***
Common Name	Plate, fixation, bone Screw, fixation, bone
Product Code, Classification Name	PLF – Bone Wedge HRS – Plate, Fixation, Bone HWC – Screw, Fixation, Bone
CFR	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	K140531: *Wright Medical Technology, Inc. BIOFOAM® Bone Wedge* K141635: *Arthrex iBalance® TKA System*
Purpose of Submission	This **traditional 510(k) premarket notification** is submitted to obtain clearance for the ***Arthrex BioSync Bone Wedge***.
Device Description	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.
Intended 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 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.
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.