DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 21, 2017

Arthrosurface, Inc.
Phani Puppala
Quality Coordinator
28 Forge Parkway
Franklin, Massachusetts 02038

Re: K162391
Trade/Device Name: AlignMATE™ Lapidus Arthrodesis 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: January 25, 2017
Received: January 26, 2017

Dear Mr. Puppala:

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/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,

Mark N. Melkerson -S

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

Enclosure

## Section 4 Indications for Use Statement

510(k) Number (if known): K162391

Device Name: AlignMATE™ Lapidus Arthrodesis System

**Indications for Use:**

Intended for the treatment of fracture fixation, osteotomies (ex. Akin, Chevron, Scarf, Weil), reconstruction, revision surgery and arthrodesis of small bones in the upper and lower extremities.

Prescription Use ___√____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Section 5 510(k) Summary**

# Special 510(k): Device Modification

## AlignMATE™ Lapidus Arthrodesis System


**510(k) Owner:**

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**Establishment Registration Number:** 3004154314

**Date of Preparation:** February 16, 2017

**Confidentiality:** Reference Section 3

**Proprietary Name:** AlignMATE™ Lapidus Arthrodesis System

**Common Name:** Bone Plates and Screws

**Device:** Plate, Fixation, Bone
Screw, Fixation, Bone

**Regulation Description:** Single/multiple component metallic bone fixation appliances and accessories.
Smooth or threaded metallic bone fixation fastener.

**Regulation Number:** 888.3030
888.3040

**Device Class:** Class II

**Review Panel:** Orthopedic

**Product Code:** HRS; HWC

## Intended Use

Intended for the treatment of fracture fixation, osteotomies (ex. Akin, Chevron, Scarf, Weil), reconstruction, revision surgery and arthrodesis of small bones in the upper and lower extremities.

## Device Description

The AlignMATE™ Lapidus Arthrodesis System consists of bone plates and bone screws (locking, non-locking and interfragmentary), which are intended to be used for surgical fusion or arthrodesis between two bone segments (ex. 1st metatarsal-cuneiform fusion as in a Lapidus procedure). All implant components are manufactured from implant grade titanium alloy.

## Substantial Equivalence Information

Arthrosurface, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the AlignMATE™ Lapidus Arthrodesis System is substantially equivalent in indications and design principles to the following predicate and/or reference devices, which have been previously cleared by the FDA:

Primary Predicate
Pinit® Small Bone Fusion System (K140617, Cleared on 04/25/2014)

Additional Predicate(s)
CheckMate® Metatarso-Phalangeal (MTP) Arthrodesis System (K113762, Cleared on 02/06/2012)

The fundamental scientific technology of the proposed device has not changed relative to the predicate devices.

- Has the same Indications for Use,
- Uses the same operating principle,
- Is manufactured using common orthopedic implant materials – Titanium alloy,
- Utilizes the same instrumentation for proper placement,
- Is packaged and sterilized using the same materials and processes.

In support of this submission, the following non-clinical tests and/or analysis were performed for the Subject Device:

- Device Comparative Analysis
- Mechanical Testing – Bending, Torsional, Insertion/ Removal, Pullout Tests per ASTM Standards
- A Kinetic Chromogenic LAL Test for Devices which meets the standard limit of 0.5 EU/mL or 20 EU/ Device per United States Pharmacopeia (USP) Chapter <85> Bacterial Endotoxins Test, USP Chapter <161> Transfusion and Infusion Assemblies and Similar Medical Devices, and AAMI ST72:2002/R2010, Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing.

The results have demonstrated that the AlignMATE™ Lapidus Arthrodesis System is substantially equivalent to the predicate devices.