December 22, 2017

Arthrosurface, Inc.
Dawn Wilson
VP, Quality & Regulatory
28 Forge Parkway
Franklin, Massachusetts 02038

Re: K172383
Trade/Device Name: Arthrosurface Bone Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 10, 2017
Received: November 14, 2017

Dear Ms. Wilson:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

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

Enclosure

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)*

K172383

Device Name
Arthrosurface Bone Screws

Indications for Use *(Describe)*

The Arthrosurface Bone Screws (2.0-3.0 mm solid and 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 Arthrosurface Bone Screws (3.5 mm and larger, solid and 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, shoulder, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5 510(k) Summary

510(k) Owner:	Arthrosurface, Inc. 28 Forge Parkway Franklin, MA 02038 Tel: 508.520.3003 Fax: 508.528.4604
Contact:	Dawn Wilson VP, Quality & Regulatory

Date of Preparation:	December 14, 2017
Trade Name:	Arthrosurface Bone Screws
Common Name:	Screw, Fixation, Bone
Device:	Smooth or Threaded Metallic Bone Fixation Fastener
Classification Regulation:	Regulation Number 21 CFR 888.3040
Device Class:	Class II
Review Panel:	Orthopedic
Product Code:	HWC

Device Intended Use

The Arthrosurface Bone Screws (2.0-3.0 mm solid and 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.

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Device Description

The Arthrosurface Bone Screws have diameters ranging from 2.0 mm to 4.0 mm and lengths ranging from 8 mm to 50 mm. The screws are either partially or fully threaded, solid or cannulated, self-tapping or self-drilling and are manufactured from implant grade stainless steel or titanium alloy. Depending on their size, these bone screws are intended to be used for different indications for use.

Substantial Equivalency:

The intended use, materials, and application of the Proposed Device are substantially equivalent to the following previously cleared and commercially marketed predicate devices:

Primary Predicate(s)

- Arthrex Low Profile Screws K143614

Additional Predicate(s)

- Arthrex Fracture System K112437
- Arthrex Low Profile Screws K103705
- Synthes Cortical Screws K112583
- Arthrosurface Bone Screws K161539

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

- Has similar indications for use
- Has similar device designs
- Uses the same operating principle
- Is manufactured using the same Stainless Steel and Titanium implant materials
- Is packaged and sterilized using the same materials and processes

The following non-clinical testing was performed on the Arthrosurface Bone Screws:

- Torque to failure, insertion/removal torque and axial pullout force tests per ASTM F543
- A Kinetic Chromogenic LAL Test for Devices that 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 safety and effectiveness of using the Arthrosurface Bone Screws is adequately supported by the substantial equivalence and performance testing information provided within this Premarket Notification. The results have demonstrated that the Arthrosurface Bone Screws are substantially equivalent to the predicate devices.