



Food and Drug Administration
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June 30, 2016

Arthrosurface, Incorporated
Ms. Dawn Wilson
Vice President, Quality & Regulatory
28 Forge Parkway
Franklin, Massachusetts 02038

Re: K161539

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: June 2, 2016
Received: June 3, 2016

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 Parts 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,

Lori A. Wiggins -S

for
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): K161539

Device Name: Arthrosurface Bone Screws

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 ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5 510(k) Summary**Special 510(k): Device Modification**
Arthrosurface Bone Screws

510(k) Owner: Arthrosurface, Inc.
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Establishment Registration Number: 3004154314

Date of Preparation: June 24, 2016

Confidentiality: Reference Section 3

Proprietary Name: Arthrosurface Bone Screws

Common Name: Bone Screws

Device: Screw, Fixation, Bone

Regulation Description: Smooth or threaded metallic bone fixation fastener

Regulation Number: 888.3040

Device Class: Class II

Review Panel: Orthopedic

Product Code: 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 Arthrosurface Bone Screws have a diameter of 2.0/2.7 mm and are made available in lengths varying from 8 mm to 24 mm with 2 mm increments. The bone screws have a snap-off feature and are designed to work with a powered wire driver, and are manufactured from implant grade stainless steel or titanium alloy.

Substantial Equivalence Information

Arthrosurface, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the Arthrosurface Bone Screws are 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

CheckMate[®] Small Bone Fusion System (K122334, Cleared on 11/28/2012)

Additional Predicate(s)

PinIt[®] Small Bone Fusion System (K140617, Cleared on 04/25/2012)

Reference Device(s)

Merete TwistCut[™] Snap-Off Bone Screw (K051323, Cleared on 07/07/2005)

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 – Stainless Steel and 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 Analyses
- A Kinetic Chromogenic LAL Test for Devices was used to determine the device is non-pyrogenic.

The results have demonstrated that the ArthroSurface Bone Screws are substantially equivalent to the predicate devices.