Section 5 510(k) Summary

Pinit™ Small Bone Fusion System
Special 510(k): Device Modification

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
Tel: 508.520.3003
Fax: 508.528.4604
dwilson@arthrosurface.com

Establishment Registration Number: 3004154314

Date of Preparation: March 25, 2014

Confidentiality: Reference Section 3

Proprietary Name: Pinit™ Small Bone Fusion System

Common Name: Bone Plates and Screws

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 Pinit™ Small Bone Fusion System consists of 2-hole bone plates made available in three length options and two thickness options, and 2.0 mm and 2.7 mm diameter bone screws having lengths varying from 8 mm to 24 mm. The bone plate is pre-assembled with a suture loop intended to provide a traction force required to achieve compression between bone segments. The bone screws have a snap-off feature designed to work with the plates and/or as standalone bone fixation fasteners. The bone plates and screws are manufactured from implant grade stainless steel.

The only modification made in this submission was the addition of bone plates having the same design profile with a different thickness. Also, the Trade/Proprietary Name was changed from CheckMate™ to Pinit™.

Substantial Equivalence Information

Arthrosurface, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the Pinit™ Small Bone Fusion System is substantially equivalent in indications and design principles to the following predicate devices, which have been previously cleared by the FDA:

CheckMate™ Small Bone Fusion System (K122334, Cleared on 11/28/2012)
Aptus® 1.5 TriLock (K102537, Cleared on 12/10/2010)
Arthrex Small Fragment Plates and Screws (K040907, Cleared on 07/01/2004)

The fundamental scientific technology of the proposed device has not changed relative to the predicate device (K122334).

- Have the same Indications for Use,

- Use the same operating principle,
- Have the same design profile,
- Manufactured using the same material,
- Have the same shelf life,
- Are packaged and sterilized using the same materials and processes.

In support of this submission, the following non-clinical tests and analysis have been performed for the Subject Device:

- Bending Moment/Flexural Strength Testing
- Engineering Analyses/Calculations using Bending Theory

The results have demonstrated that the Arthrosurface Pinit™ Implants are substantially equivalent to the predicate devices.

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

April 25, 2014

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

Re: K140617
Trade/Device Name: Pinit™ Small Bone Fusion System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: March 25, 2014
Received: March 26, 2014

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Ronald P. Jean -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): K140617

Device Name: Pinit™ Small Bone Fusion 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)

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(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K140617