August 14, 2019

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

Re: K190261
Trade/Device Name: BOSS Toe Fixation System
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe Joint Phalangeal (Hemi-Toe) Polymer Prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: July 17, 2019
Received: July 18, 2019

Dear Dawn 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For CAPT Raquel Peat, PhD, MPH, USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K190261

Device Name
BOSS Toe Fixation System

Indications for Use *(Describe)*

Hemi-arthroplasty implant for the metatarsophalangeal joint for use in the treatment of patients with degenerative and post-traumatic arthritis in the metatarsal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus or hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint.
The device is a single use implant intended to be used with bone cement or without bone cement.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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."*

**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
Tel: 508.520.3003
Fax: 508.528.4604
dwilson@arthrosurface.com

**Establishment Registration Number:** 3004154314

**Date of Preparation:** August 14, 2019

**Proprietary Name:** BOSS™ Toe Fixation System

**Common Name:** MTP Fixation Component

**Device:** Prosthesis, Toe, Hemi-, Phalangeal

**Regulation Description:** 888.3730
**Review Panel:** Orthopedic
**Product Code:** KWD

**Device Description**

The Arthrosurface MTP implant incorporates an articular resurfacing component and a taper post component that mate together via a morse taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface.

Per K132496, the MTP can be used in conjunction with the Arthrosurface Proximal Phalanx Implant as a Total Toe option. K132496 also cleared the most recent version of the mating articular component.

Fixation components are being included in the system that contain an additional ring of material intended to improve stabilization in a first metatarsal that presents with a distal bone void. The articulating component and taper configuration are unchanged. The phalangeal implant is unchanged.

**Indications for Use**

Hemi-arthroplasty implant for the metatarsophalangeal joint for use in the treatment of patients with degenerative and post-traumatic arthritis in the metatarsal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus or hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint.
The device is a single use implant intended to be used with bone cement or without bone cement.

**Substantial Equivalence Information**

Arthrosurface, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the MTP fixation component is substantially equivalent in indications and design principles to the following predicate devices, which have been previously cleared by the FDA:

HemiCAP® MTP Resurfacing Hemi-Arthroplasty Implant (fixation component) K131377

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 the same implant grade orthopedic materials
- Utilizes the same instrumentation for proper placement
- Is packaged and sterilized using the same materials and processes

**Support**

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

- Device comparative analysis
- Device mechanical strength including pullout and shear
- Cadaveric evaluation (e.g. Radiographs, Axial Pullout)
- 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.

**Conclusion**

The results have demonstrated the safety and effectiveness of the Arthrosurface® BOSS Toe Fixation system along with substantial equivalence to the HemiCAP® system (predicate device K131377).