



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

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

April 11, 2016

Re: K152454

Trade/Device Name: HemiCAP<sup>®</sup> MTP Resurfacing Hemi-Arthroplasty System

Regulation Number: 21 CFR 888.3730

Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis

Regulatory Class: Class II

Product Code: KWD

Dated: March 10, 2016

Received: March 14, 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,

**Mark N. Melkerson -S**

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

Enclosure

<b>Section 4    Indications for Use Statement</b>
---

510(k) Number (if known): K152454

Device Name:        HemiCAP® MTP Resurfacing Hemi-Arthroplasty System

**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.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
 NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Section 5 510(k) Summary**

**HemiCAP<sup>®</sup> MTP Resurfacing Hemi-Arthroplasty System  
Phalangeal HemiCAP<sup>®</sup>**

**Special 510(k) Submission: 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](mailto:dwilson@arthrosurface.com)

**Establishment Registration  
Number:**

3004154314

**Date of Preparation:**

March 30<sup>th</sup>, 2016

**Confidentiality:**

Reference Section 3

**Proprietary Name:**

HemiCAP<sup>®</sup> MTP Resurfacing Hemi-  
Arthroplasty System-Phalangeal HemiCAP<sup>®</sup>

**Common Name:**

MTP Hemi-Toe Prosthesis

**Device:**

Prosthesis, Toe, Hemi, Phalangeal

**Regulation Description:**

Toe joint phalangeal (hemi-toe) polymer  
prosthesis

**Regulation Number:**

888.3730

**Device Class:**

Class II

**Review Panel:**

Orthopedic

**Product Code:** KWD

### **Intended 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.

### **Device Description**

The HemiCAP<sup>®</sup> MTP Resurfacing Hemi-Arthroplasty System-Phalangeal HemiCAP<sup>®</sup> incorporates an articular resurfacing component and a cancellous taper post fixation component that mate together via a taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface.

The enclosed phalangeal base HemiCAP<sup>®</sup> implant is intended for hemi-arthroplasty only. Do not use in conjunction with metallic metatarsal implant.

The present device modification includes the addition of modified phalangeal base (concave) implants and a corresponding taper post to the existing system.

### **Substantial Equivalence Information**

Arthrosurface, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the HemiCAP<sup>®</sup> MTP Resurfacing Hemi-Arthroplasty System is substantially equivalent in indications and design principles to the following predicate devices, which have been previously cleared by the FDA:

- The sponsor's previously cleared CAP<sup>®</sup> Great Toe Resurfacing Hemi-Arthroplasty (K031859, Cleared on 02/18/2004)
- The sponsor's previously cleared HemiCAP<sup>®</sup> MTP Resurfacing Hemi-Arthroplasty System (K131377, Cleared on 11/19/2013)
- The sponsor's previously cleared Arthrosurface<sup>®</sup> Total Toe – Proximal Phalanx Implant (K132496, Cleared on 02/26/2014)

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

- Has the same Indications for Use,
- Has the same operating principle,
- Is manufactured using the same material,
- Has the same shelf life,
- Is packaged and sterilized using the same materials and processes.

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

- Comparative Engineering Analyses
- Comparative Mechanical Testing
  - Assembly and Disassembly Testing
  - Resistance to Torsion Testing
  - Cyclic Fatigue Testing
  - Fretting Corrosion Testing
  - Pull-out Strength Testing
  - Finite Element Analysis

The results have demonstrated the safety and effectiveness of the HemiCAP<sup>®</sup> MTP Resurfacing Hemi-Arthroplasty System-Phalangeal HemiCAP<sup>®</sup> Implants along with substantial equivalence to the predicate devices.