June 14, 2018

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

Re: K181280
Trade/Device Name: Patello-Femoral Wave (Kahuna) Arthroplasty System
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee Joint Patellofemoral Polymer/Metal Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRR
Dated: May 10, 2018
Received: May 15, 2018

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. 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 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)*

K181280

Device Name

Patello-Femoral Wave (Kahuna) Arthroplasty System

Indications for Use *(Describe)*

Indications for Use:

Intended to be used in cemented arthroplasty in patients with osteoarthritis limited to the distal patello-femoral joint, patients with a history of patellar dislocation or patellar fracture, and those patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release, etc.) where pain, deformity or dysfunction persists.

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.

510(k) Summary

Special 510(k): Device Modification
Patello-Femoral Wave*Kahuna* Arthroplasty System

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:	May 10, 2018
Proprietary Name:	Patello-Femoral Wave*Kahuna* Arthroplasty System
Common Name:	Knee Joint Patello-Femoral Arthroplasty System
Device:	Prosthesis, Knee, Patello/Femoral, Semi-Constrained, Cemented, Metal/Polymer
Regulation Description:	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
Regulation Number:	888.3540
Device Class:	Class II
Review Panel:	Orthopedic
Product Code:	KRR

Device Description

The Patello-Femoral Wave*Kahuna* Arthroplasty System is a line extension to the Sponsor's previously cleared and commercially marketed HemiCAP™ Patello-Femoral Resurfacing System.

The line extension consists of a larger femoral component for increased coverage of the trochlear groove. The additional sizes will address larger defects of the superior aspect of the trochlea and provide greater coverage superiorly. The system also includes larger mating UHMWPE patella components as described within.

The larger PF Kahuna trochlear Patello-Femoral Wave*Kahuna* articular component is designed to mate with the currently marketed Arthrosurface Patello-Femoral fixation component.

The majority of the implantation technique steps are the same. The PF Kahuna trochlear component is implanted using the same Instrumentation Set as with the HemiCAP™ Patello-Femoral Resurfacing System, with the addition of a reaming operation to create the superior ream. The reamers, associated implant trials etc. are contained within an adjunct Patello-Femoral Wave*Kahuna* Instrumentation Kit.

Indications for Use

The Patello-Femoral Wave*Kahuna* Arthroplasty System is intended to be used in cemented arthroplasty in patients with osteoarthritis limited to the distal patello-femoral joint, patients with a history of patellar dislocation or patellar fracture, and those patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release, etc.) where pain, deformity or dysfunction persists.

Substantial Equivalence Information

Arthrosurface, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the Patello-Femoral Wave*Kahuna* Arthroplasty System is substantially equivalent in indications and design principles to the following predicate devices, which have been previously cleared by the FDA:

HemiCAP Patello-Femoral Resurfacing Prosthesis	K071413

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 similar 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 Analysis
- Contact Area Analysis
- Lateral Subluxation Testing
- 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 Patello-Femoral Wave*Kahuna* Arthroplasty System along with substantial equivalence to the predicate device (K071413).