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

April 18, 2018

Re: K173964
Trade/Device Name: OVOMotion™ Shoulder Arthroplasty System
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder Joint Humeral (Hemi-Shoulder) Metallic Uncemented Prosthesis
Regulatory Class: Class II
Product Code: HSD, KWS
Dated: January 17, 2018
Received: January 18, 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Katherine D. Kavlock -S

for
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)*

K173964

Device Name

OVOMotion Shoulder Arthroplasty System

Indications for Use *(Describe)*

Indications for Use:

For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable.

The device is a single use implant intended to be used for hemiarthroplasty or in conjunction with the Arthrosurface glenoid component for total shoulder arthroplasty.

Both humeral and glenoid components of the OVOMotion™ Shoulder Arthroplasty System are intended for cemented use only.

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.

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Section 5 510(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
Date of Preparation:	December 27, 2017
Trade Name:	OVOMotion™ Shoulder Arthroplasty System
Common Name:	Shoulder Arthroplasty System
Classification Regulations:	888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis.
Product Codes:	HSD, KWS
Device Class:	Class II
Review Panel:	Orthopedic

Device Indications for Use

For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable.

The device is a single use implant intended to be used for hemiarthroplasty or in conjunction with the Arthrosurface glenoid component for total shoulder arthroplasty.

Both humeral and glenoid components of the OVOMotion™ Shoulder Arthroplasty System are intended for cemented use only.

Device Description

The OVOMotion™ Humeral prosthesis incorporates an articular resurfacing component and a 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 Arthrosurface OVOMotion™ Shoulder Arthroplasty System is intended as hemiarthroplasty or in conjunction with Sponsor's previously cleared and commercially marketed glenoid prosthesis (K091196) to repair and replace a shoulder joint when both articular surfaces of the joint are affected.

Humeral articular components are manufactured from CoCrMo and mate with corresponding Ti fixation component. Glenoid components are made from Ultra High Molecular Weight Polyethylene (UHMWPE). Both humeral and glenoid components are available in multiple sizes and curvatures and are intended to be implanted using bone cement.

Substantial Equivalency:

Arthrosurface, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the OVOMotion Shoulder Arthroplasty System is substantially equivalent in indications and design principles to the following predicate(s) and/or reference devices, which have been previously cleared by the FDA:

Primary Predicate:

- Arthrosurface HemiCAP OVO Humeral System K142942

Additional Predicate:

- Catalyst CSR Shoulder System K152825

Reference Device:

- Arthrosurface GRS™ Glenoid Resurfacing System K091196
- Arthrosurface HemiCAP® Shoulder K023096

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

- Has similar Indications for Use,
- Uses the same operating principle,
- Is manufactured using common orthopedic implant 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
- Humeral Head mechanical testing – Assembly & Disassembly, Resistance to Torque, Cyclic Fatigue, Fretting Corrosion, Static Compression to Failure, Shear Testing and Lever Out.
- 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.

The results have demonstrated that the OVOMotion™ Shoulder Arthroplasty System is substantially equivalent to the predicate devices.