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

June 24, 2021

Re: K203375
Trade/Device Name: OVOMotion Reverse Shoulder Arthroplasty System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: May 24, 2021
Received: May 25, 2021

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,

Michael Owens
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K203375

Device Name

OVOMotion Reverse Shoulder Arthroplasty System

Indications for Use *(Describe)*

The OVOMotion Reverse Shoulder Arthroplasty System is intended for primary total shoulder replacement in a reverse shoulder configuration. The device is indicated for a patient with painful, disabling joint disease of the shoulder resulting from degenerative arthritis or rheumatoid arthritis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The patient's joint must have gross rotator cuff deficiency, a functional deltoid muscle and be anatomically and structurally suited to receive the selected implants.

Glenoid Baseplate components are intended for cementless use with the addition of screw fixation. The Humeral Stem components are intended for both cemented and cementless use.

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.

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 K203375

510(k) SUMMARY

Arthrosurface's OVOMotion Reverse Shoulder Arthroplasty System

Submitter

Arthrosurface, Inc.
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Contact Person: Dawn Wilson
dwilson@anika.com

Date Prepared: November 16, 2020

510(k) Number: K203375

Name of Device: OVOMotion Reverse Shoulder Arthroplasty System

Common or Usual Name: Shoulder Prosthesis, Reverse Configuration

Classification Name: 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis

Regulatory Class: II

Product Code: PHX

Predicate Devices

Primary Predicate - Stryker Orthopedics ReUnion Reverse Shoulder Arthroplasty System (RSA) (K183039).

Reference Devices- Arthrosurface's OVOMotion Shoulder Arthroplasty System (K173964)

Arthrosurface WristMotion (K200718) to support the CP Ti coating

Device Description

The OVOMotion Reverse Shoulder Arthroplasty System (RSA) is a system of components intended for total shoulder replacement in a reverse shoulder configuration. The humeral side of the system is comprised of a humeral cup and humeral insert which are attached to the Arthrosurface TSA Humeral Stem using an adapter ring. The glenosphere is implanted with the GlenoidBaseplate onto the glenoid side of the joint fixated with locking Center and Peripheral Screws.

Indications for Use

The OVOMotion Reverse Shoulder Arthroplasty System is intended for primary total shoulder replacement in a reverse shoulder configuration. The device is indicated for a patient with painful, disabling joint disease of the shoulder resulting from degenerative arthritis or rheumatoid arthritis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The patient's joint must have gross rotator cuff deficiency, a functional deltoid muscle and be anatomically and structurally suited to receive the selected implants.

Glenoid Baseplate components are intended for cementless use with the addition of screw fixation. The Humeral Stem components are intended for both cemented and cementless use.

Summary of Technological Characteristics

The OVOMotion Reverse Shoulder Arthroplasty System is substantially equivalent to the predicate device, Stryker ReUnion Reverse Shoulder, having a modular design of similar components and with CoCr and UHMWPE articulating surfaces in a reverse shoulder arthroplasty configuration.

The humeral stems of the subject and predicate system are both made from Ti6Al4V and contain a metallic coating around the neck of the prosthesis. Both systems have a fluted distal end and are intended for cemented or cementless fixation. The size range is comparable, with the subject device having a slightly smaller size range. Both systems allow the same stem to be used in both normal and reverse configurations and use taper connections between the stem and the articulating humeral component. While the predicate allows for direct connection of the humeral tray to the stem, the subject device requires use of an adapter ring to change the size of the taper. The company has assessed the assembly, axial disassembly, torque out and lever out loads of this connection as compared to predicates and found them to be equivalent.

The humeral trays of both systems are available in the same sizes and attach to the other metallic components using a taper. Both trays attach to an UHMWPE liner which is pressfit

into the tray with both axial and rotational locking mechanism. The company has assessed the disassembly loads of the subject device as compared to the Stryker predicate and found them to be equivalent. The underside geometry of the trays differ between the systems. While Stryker uses a more traditional planar cut, the underside of the tray of the subject device is shaped to closely match the 3D geometry of the prepared humeral head. Notably, this geometry matches the geometry cleared for the humeral articulating components in OVOMotion's traditional shoulder system (K173964).

The humeral liners of both systems are available in the same sizes but with differing heights. A smaller height range is needed for the subject device as the adapter sleeve also provides for height variation. While the predicate has both constrained and unconstrained liners, the subject device offers only unconstrained liners. The company has assessed the subluxation loads of the subject device as compared to the predicate and found them equivalent. The subject device is only available in conventional UHMWPE while the predicate is available in X3 UHWMPE material. The company has conducted wear testing ofthe subject device to demonstrate comparable wear performance to the DJO Encore Reverse Shoulder Prosthesis (K052086).

The glenosphere of both systems are made from highly polished CoCr per ASTM F799 and are available in the same sizes. Both systems offer concentric and eccentric heads and lateral offsets.

The glenoid baseplate of both systems is made from Ti6Al4V and contains a metallic coating on its bone-facing underside. Both baseplates are intended for screwed, uncemented fixation and contain a larger, central locking screw and 4 peripheral screws. The size of the base plates differ. The subject device also offers a 0 or 1 mm offset for the baseplate, not available for the predicate. The addition of the offset only serves to provide the surgeon more options to match patient anatomy and does not raise different questions. Both systems use a taper connection between the baseplate and glenosphere. The company has performed axial assembly and disassembly, resistance to torque, and compression to failure per ASTM F2009 for the subject and predicate device and determined that they have equivalent performance.

The screws of both systems are made from Ti6Al4V and are provided in comparable diameter and length ranges. The company has conducted ASTM F543 testing to determine insertion and removal torque, torque to failure, and axial pull-out of the subject device to demonstrate adequate performance. In addition, the company conducted glenoid loosening testing per ASTM F2028 to determine edge displacement and cyclic fatigue which also demonstrated good glenoid fixation.

Finally, the stem configuration of the total construct was subjected to axial fatigue testing to demonstrate equivalent mechanical performance of the overall system.

Performance Data

The following tests were conducted to establish equivalence:

- Disassociation testing of the humeral insert from humeral tray per ASTM F1820
- Axial, torque and lever out taper disassociation strength testing of the humeral tray to stem, and glenosphere to baseplate
- Compression loading of humeral tray to stem and glenosphereto baseplate
- Subluxation testing per ASTM F1223
- Glenoid loosening testing per ASTM F2028
- Bone screw testing per ASTM F543
- Multiaxial wear testing
- Total construct fatigue testing of stem
- Simulated CAD modeling and Cadaveric Range of Motion

No animal or clinical tests were conducted to establish equivalence.

Conclusions

The OVOMotion Reverse Shoulder Arthroplasty System is as safe and effective as the Stryker ReUnion RSA. The OVOMotion Reverse Shoulder Arthroplasty System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the OVOMotion ReverseShoulder Arthroplasty System and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the OVOMotion Reverse Shoulder Arthroplasty System is as safe and effective as the Stryker ReUnion RSA. Thus, the OVOMotion Reverse Shoulder Arthroplasty System is substantially equivalent.