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

October 15, 2020

Re: K200718
Trade/Device Name: Arthrosurface WristMotion Total Wrist Arthroplasty System
Regulation Number: 21 CFR 888.3800
Regulation Name: Wrist Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWJ
Dated: September 11, 2020
Received: September 14, 2020

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,

Vesa Vuniqi
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K200718

Device Name
Arthrosurface Total Wrist Arthroplasty System

Indications for Use *(Describe)*

The Arthrosurface Total Wrist Arthroplasty System is indicated for replacement of the painful wrist joint due to rheumatoid arthritis, oseto-arthritis, or post-traumatic arthritis.
The device is a single-use implant intended to be used with 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.

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510(k) Summary

510(k) Owner:	Arthrosurface 28 Forge Parkway Franklin, MA 02038 Tel: 508.520.3003 Fax: 508.528.4604
Contact:	Dawn Wilson VP, Quality & Regulatory
Date of Preparation:	March 17, 2020
Trade Name:	Arthrosurface WristMotion™ Wrist Arthroplasty System
Common Name:	Total Wrist Arthroplasty System
Device:	Prosthesis, Wrist, 3 Part Metal-Plastic-Metal Articulation, Semi-Constrained
Classification Regulation:	Wrist joint metal/polymer semi-constrained cemented prosthesis
Device Class:	Class II
Review Panel:	Orthopedic
Product Code:	JWJ

Device Description

The Arthrosurface Total Wrist Arthroplasty (TWA) System is a modular joint restoration system that consists of both a radial implant assembly and carpal implant assembly. The radial implant assembly is comprised of a metallic stemmed tray component and Ultra-High-Molecular-Weight-Polyethylene (UHMWPE) articular component. The carpal implant assembly consists of a taper post component, a carpal plate, an articular component and two auxiliary bone screw components, all of which are metallic. The system is designed to replace the radiocarpal joint (distal radius and proximal row of carpal bones) and is intended to alleviate pain while restoring functionality and mobility of the joint.

Indications for Use

The Arthrosurface Total Wrist Arthroplasty System
Indicated for replacement of the painful wrist joint due to rheumatoid arthritis, osteoarthritis, or post-traumatic arthritis.
The device is a single-use implant intended to be used with bone cement.

Substantial Equivalence
Arthrosurface has demonstrated that for the purposes of the FDA's regulation of medical devices, the Arthrosurface Total Wrist Arthroplasty System is substantially equivalent in indications for use and design principles to the following predicate devices, which have been previously cleared by the FDA:

Primary Predicate	Avanta Orthopaedics Inc. Total Wrist (K021859) *Now Stryker ReMotion*
Reference Predicate Devices	Biomet Maestro Total Wrist System (K042032) Arthrosurface HemiCAP Wrist (K141920)

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

- Total arthroplasty implant for the wrist joint
- Same indications for use
- Same implant materials
- Same radial stem fixation and central carpal fixation with 2 auxiliary screws

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

- Bone Screws – insertion & removal, torsion to failure, axial pullout
- Assembly / Disassembly
- Resistance to Torque
- Static & Cyclic Edge Testing
- Fretting Corrosion
- Constraint testing (Subluxation)
- Comparative Engineering Analyses (ROM, Contact Area etc.)
- 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 Bacterial Endotoxins Test, USP Chapter 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 Total Wrist Arthroplasty System along with substantial equivalence to the predicate devices.