May 19, 2022

Arthrex Inc.
Ivette Galmez
Regulatory Affairs Principal Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K221232
Trade/Device Name: Univers Revers Humeral Cup Implant
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder Joint Humeral (Hemi-Shoulder) Metallic Uncemented Prosthesis
Regulatory Class: Class II
Product Code: HSD, PHX
Dated: April 27, 2022
Received: April 29, 2022

Dear Ivette Galmez:

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,

Lixin Liu, Ph.D.
Acting 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)*
K221232

Device Name

Univers Revers Humeral Cup Implant

Indications for Use *(Describe)*

The Univers Revers Shoulder Prosthesis System is indicated for use in a grossly rotator cuff deficient glenohumeral joint with severe arthropathy or a previously failed joint replacement with a gross rotator cuff deficiency. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The Univers Revers Shoulder Prosthesis System is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

(Humeral) Stems are intended for cemented or cementless applications for use with Arthrex Humeral SutureCups. The glenoid baseplate is CaP coated and is intended for cementless use with the addition of screws for fixation.

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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510(k) Summary

Date Prepared	May 18, 2022
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Ivette Galmez Regulatory Affairs Principal Specialist 1-239-643-5553, ext. 71263 ivette.galmez@arthrex.com
Name of Device	Univers Revers Humeral Cup Implant
Common Name	Shoulder Prosthesis
Product Code	HSD, PHX
Classification Name	21 CFR 888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis 21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class	II
Predicate Device	K161782: Arthrex Univers Revers Shoulder Prosthesis System
Reference Device	K142863: Arthrex Univers Revers Shoulder Prosthesis System K191960: Arthrex Univers Revers Modular Glenoid System K173900: Arthrex Univers Revers Modular Glenoid System
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for size 33 humeral cup components for use with the Univers Revers Shoulder Prosthesis System cleared under K161782.
Device Description	The subject devices are comprised of size 33 humeral suture-cups, spacers and inserts. The subject devices are made of either titanium or UHMWPE. The subject devices are smaller versions than those cleared in K161782 and K142863. The subject devices are compatible with the Univers Revers Shoulder Prosthesis System and Univers Revers Modular Glenoid System devices.
Indications for Use	The Univers Revers Shoulder Prosthesis System is indicated for use in a grossly rotator cuff deficient glenohumeral joint with severe arthropathy or a previously failed joint replacement with a gross rotator cuff deficiency. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The Univers Revers Shoulder Prosthesis System is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. (Humeral) Stems are intended for cemented of cementless applications for use with Arthrex Humeral SutureCups. The glenoid baseplate is CaP coated and is intended for cementless use with the addition of screws for fixation.
Summary of Technological Characteristics	The subject devices are made of the same materials as the predicates. The subject devices have the same intended use/indications, packaging, shelf life and sterilization as the predicates. This submission expands the size range of the cleared humeral components (suture cup, spacer, and inserts) by introducing the smallest size 33 humeral implants.
Performance Data	Mechanical testing (i.e., PE liner/cup interface per ASTM F1820) was performed.
Conclusion	The subject devices are substantially equivalent to the predicate devices in which the basic design features and intended use are the same. The mechanical testing data demonstrates that the subject device performance is equivalent to the predicate device for the desired indications. Any differences between the subject and the predicate device are considered minor and do not raise different questions regarding safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the subject device is substantially equivalent to the currently marketed predicate device.