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

February 12, 2024

Re: K233260
Trade/Device Name: Univers Revers CA Head and Adapter
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: Class II
Product Code: HSD
Dated: January 10, 2024
Received: January 10, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2024.02.12 11:08:41 -05'00'

for: Farzana Sharmin, PhD
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233260

Device Name

Univers Revers CA Head and Adapter

Indications for Use *(Describe)*

The Univers Revers CA humeral head and adapters are indicated for:

• salvage of a failed reverse total shoulder, with an irreparable rotator cuff tear and a well-fixed humeral stem, to an anatomic hemi-shoulder replacement; or

• conversion of a primary reverse total shoulder, for the relief of pain secondary to severe rotator cuff arthropathy and an irreparable rotator cuff tear, to anatomic hemi-shoulder replacement when insufficient glenoid bone stock is encountered intraoperatively after the humeral stem has been implanted.

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.

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	February 9, 2024
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Ivette Galmez Regulatory Affairs Principal Specialist 1 (239) 643-5553 x 71263 ivette.galmez@arthrex.com
Trade Name	Univers Revers CA Head and Adapter
Common Name	Shoulder Prosthesis
Product Code	HSD
Classification Name	21 CFR 888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class	II
Predicate Device	K151527: Arthrex Univers Revers CA Heads and Adapters
Reference Devices	K071032: Arthrex Univers II Shoulder Prosthesis K221232: Univers Revers Humeral Cup Implant K230366: Arthrex Univers Revers Monoblock Stem Size 4/33 K161782: Arthrex Univers Revers Shoulder Prosthesis System K230513: Arthrex Univers Apex OptiFit Humeral Stems
Purpose of Submission	This 510(k) premarket notification is submitted to obtain clearance for the Univers Revers CA Head and Adapter which is smaller than the predicate device.
Device Description	The subject device is a line extension to the Arthrex Univers Revers CA Heads and Adapters cleared in K151527. The subject device components are smaller and are made of the same materials (cobalt chromium, titanium, and UHMWPE) as the predicate. The subject devices are designed for use with the Arthrex implantable devices cleared in K221232, K230366, K161782, K142863 and K170414. The subject devices are labeled with MRI conditional claims in accordance with Arthrex labeling cleared under K230513.
Indications for Use	The Univers Revers CA humeral head and adapters are indicated for: • salvage of a failed reverse total shoulder, with an irreparable rotator cuff tear and a well-fixed humeral stem, to an anatomic hemi-shoulder replacement; or • conversion of a primary reverse total shoulder, for the relief of pain secondary to severe rotator cuff arthropathy and an irreparable rotator cuff tear, to anatomic hemi-shoulder replacement when insufficient glenoid bone stock is encountered intraoperatively after the humeral stem has been implanted. 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.
Performance Data	Dynamic fatigue testing followed by corrosion assessment per ASTM F1875, metal ion analysis, and disassembly testing per ASTM F1820 was performed. All samples met the acceptance criteria. Biocompatibility testing was conducted to demonstrate no impact to the final finished device due to the change of supplier. Bacterial Endotoxin per EP 2.6.14/USP <85> demonstrates that the subject device meets pyrogen limit specifications.
Technological Comparison	This submission expands the size range of the Univers Revers CA Heads and Adapters by introducing smaller size implants but with identical design features to the predicate. The subject device components are made of the same materials as the predicate. The subject devices have the same intended use/indications, packaging, shelf life and sterilization as the predicate.
Conclusion	The subject device is substantially equivalent to the predicate in which the basic design features and intended use/indications 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.