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

April 10, 2023

Re: K230366
Trade/Device Name: Arthrex Univers Revers Monoblock Stem Size 4/33
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, HSD
Dated: February 10, 2023
Received: February 10, 2023

Dear Tiffany Mentzel:

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,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2023.04.10 13:31:51 -04'00'

Farzana Sharmin, PhD
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)*

K230366

Device Name

Arthrex Univers Revers Monoblock Stem Size 4/33

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 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	April 10, 2023
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Tiffany Mentzel Title: Principal Regulatory Affairs Specialist Phone: (239)-643-5553 ext. 75833 Email: Tiffany.Mentzel@Arthrex.com
Trade Name	Arthrex Univers Revers Monoblock Stem Size 4/33
Common Name	Shoulder Prosthesis
Product Code	PHX, HSD
Classification Name	21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class	II
Primary Predicate Device	K130129: Univers Revers Shoulder Prothesis System
Additional Predicates	K170414: Arthrex Univers Revers Apex Humeral Stems K171841: Arthrex Shoulder System K181555: Arthrex Fracture Adapter Hemi Shoulder Prothesis K221232: Univers Revers Humeral Cup Implant
Device Description	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Univers Revers Monoblock Stem Size 4/33 as a line extension to the Arthrex Univers Revers Humeral Stems cleared under K130129 for use in the Arthrex Univers Revers Shoulder Prothesis System. The Arthrex Univers Revers Monoblock Stem Size 4/33 is a humeral stem that is manufactured from Titanium (Ti-AL-4V), coated with either Calcium Phosphate (CaP) or Hydroxyapatite (HA), and offered sterile.
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 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.
Performance Data	Dynamic fatigue testing was performed to evaluate the fatigue resilience of the proposed stem. Range of motion (ROM) of the subject device is dictated by the ROM of the mating liners and previously cleared components. Computational electromagnetic method was used to evaluate the surface SAR patterns of the Arthrex Univers Revers MonoBlock Stem under MRI radio frequency (RF) coil emissions at 64-MHz associated with 1.5Tesla and 128-MHz associated with 3Tesla MRI procedures. The surface SAR patterns within the standard ASTM phantom (ASTM F2182-19e2) were obtained. The results indicate that for the device induced heating, the maximum 1g averaged SAR values (corresponding maximum temperature rises) are located near end of the device. Based on the in-vivo modeling, the maximum temperature rise after 60 minutes exposure is less than 6 degrees Celsius under the condition of the WB SAR at 2W/kg inside tissue and WB SAR at 1W/kg inside the bone.
Technological Comparison	Compared to the predicate (K130129), the only difference is the size. The proposed line extension has the same indications for use, is manufactured from the same materials, undergo the same manufacturing processing, undergo the same sterilization process, are packaged in the same packaging configuration, and have the same shelf-life as the predicate.
Conclusion	The Arthrex Univers Revers Apex Humeral Stem is substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise questions concerning safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the proposed device is substantially equivalent to the currently marketed predicate device.