Arthrex Inc.
Courtney Smith
Manager, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108-1945

September 28, 2018

Re: K182039
Trade/Device Name: Arthrex Univers Revers Porous Coated Baseplate and Universal Glenoid Inlay
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: PHX, MBF
Dated: July 26, 2018
Received: July 30, 2018

Dear Courtney Smith:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel S. Ramsey -S
2018.09.28 10:01:59 -04'00'

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K182039

Device Name
Arthrex UNIVERS REVERS POROUS COATED BASEPLATE and UNIVERSAL GLENOID INLAY

Indications for Use *(Describe)*

The Arthrex UNIVERS REVERS POROUS COATED BASEPLATE is designed to be used as the glenoid component of the existing Univers Revers Shoulder Prosthesis System or Univers II Shoulder Arthroplasty System.

The Arthrex UNIVERS REVERS POROUS COATED BASEPLATE 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 Arthrex UNIVERS REVERS POROUS COATED BASEPLATE is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

The Arthrex UNIVERS REVERS POROUS COATED BASEPLATE is porous coated and is intended for cementless use with the addition of screws for fixation.

The Arthrex UNIVERS REVERS POROUS COATED BASEPLATE AND UNIVERSAL GLENOID INLAY are indicated for use in anatomic joint replacement(s) when conditions including severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, fracture or injury of the glenohumeral joint; non-union humeral head fractures of long duration; avascular necrosis of the humeral head; neoplastic or dysplastic diseases; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable.

For anatomic joint replacement, the Arthrex UNIVERS REVERS POROUS COATED BASEPLATE AND UNIVERSAL GLENOID INLAY are indicated to be used with the humeral components of the Arthrex Univers II Shoulder Prosthesis System for total shoulder arthroplasty. The UNIVERSAL GLENOID INLAY is intended for use with the UNIVERS REVERS POROUS COATED BASEPLATE.

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 or 510(k) Statement

Date Prepared	September 27, 2018
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Courtney Smith Manager, Regulatory Affairs 1-239-643-5553, ext. 71720 Courtney.smith@arthrex.com
Name of Device	*Arthrex UNIVERS REVERS POROUS COATED BASEPLATE AND UNIVERSAL GLENOID INLAY*
Common Name	Shoulder Prosthesis
Product Code	PHX, MBF
Classification Name	Prosthesis, Shoulder, semi-constrained metal/polymer, cemented, CFR 888.3660 Prosthesis, Shoulder, semi-constrained metal/polymer, uncemented, CFR 888.3670
Regulatory Class	II
Predicate Device	Primary – K172371: Arthrex Univers Revers Coated Baseplate Reference – K161120: Lima SMR TT Metal Back Glenoid K162068: Arrow Anatomical Porous Glenoid
Purpose of Submission	This **traditional 510(k)** premarket notification is submitted to obtain clearance for the *Arthrex UNIVERS REVERS POROUS COATED BASEPLATE AND UNIVERSAL GLENOID INLAY*.
Device Description	The Arthrex *UNIVERS REVERS POROUS COATED BASEPLATE AND UNIVERSAL GLENOID INLAY* consists of a porous coated titanium glenoid baseplate and a UHMWPE inlay bearing. The baseplate is designed to be used as the glenoid component of the existing Univers Revers Shoulder Prosthesis System or Univers II Shoulder Arthroplasty System. The baseplate is centrally anchored by a barbed post with superior and inferior multi-directional screws to ensure optimal fixation. The baseplate and inlay bearing come in three sizes to match anatomical size variations. For a reversed shoulder application, the baseplate can be paired with the Univers Revers glenosphere. For an anatomic shoulder application, the baseplate should be paired with the inlay bearing. The inlay bearing is available in two thicknesses (standards and +2mm) and in sizes corresponding to the glenoid baseplate. Pegs on the underside of the inlay bearing snap into corresponding recesses in the baseplate, ensuring a secure attachment to the bearing inlay, while at the same time minimizing angular rotation.
Indications for Use	The Arthrex UNIVERS REVERS POROUS COATED BASEPLATE is designed to be used as the glenoid component of the existing Univers Revers Shoulder Prosthesis System or Univers II Shoulder Arthroplasty System. The Arthrex UNIVERS REVERS POROUS COATED BASEPLATE 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 Arthrex UNIVERS REVERS POROUS COATED BASEPLATE is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. The Arthrex UNIVERS REVERS POROUS COATED BASEPLATE is porous coated and is intended for cementless use with the addition of screws for fixation. The Arthrex UNIVERS REVERS POROUS COATED BASEPLATE AND UNIVERSAL GLENOID INLAY are indicated for use in anatomic joint replacement(s) when conditions including severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, fracture or injury of the glenohumeral joint; non-union humeral head fractures of long duration; avascular necrosis of the humeral head; neoplastic or dysplastic diseases; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable. For anatomic joint replacement, the Arthrex UNIVERS REVERS POROUS COATED BASEPLATE AND UNIVERSAL GLENOID INLAY are indicated to be used with the humeral components of the Arthrex Univers II Shoulder Prosthesis System for total shoulder arthroplasty. The UNIVERSAL GLENOID INLAY is intended for use with the UNIVERS REVERS POROUS COATED BASEPLATE.
Performance Data	Performance testing (shear force, comparative, glenoid dynamic loosening testing and locking mechanism disassembly testing) demonstrated that the Arthrex *UNIVERS REVERS POROUS COATED BASEPLATE AND UNIVERSAL GLENOID INLAY* performs equivalently to the predicate device. Non-clinical testing demonstrates that the baseplate coating is in compliance with the FDA Guidance for Industry on Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements. The Arthrex *UNIVERS REVERS POROUS COATED BASEPLATE AND UNIVERSAL GLENOID INLAY* meets pyrogen limit specifications.
Conclusion	The proposed device is substantially equivalent to the predicate devices 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.