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

March 22, 2018

Re: K172371
Trade/Device Name: Arthrex UNIVERS REVERS COATED BASEPLATE
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: February 16, 2018
Received: February 20, 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Katherine D. Kavlock -S

for
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)*
K172371

Device Name
Arthrex Univers Revers Coated Baseplate

Indications for Use *(Describe)*
The Arthrex UNIVERS REVERS COATED BASEPLATE is designed to be used as the glenoid component of the existing Univers Revers Shoulder Prosthesis System.

The Arthrex UNIVERS REVERS 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 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 COATED BASEPLATE is 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.

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510(k) Summary or 510(k) Statement

Date Prepared	March 19, 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 COATED BASEPLATE*
Common Name	Shoulder Prosthesis
Product Code	PHX
Classification Name	Prosthesis, Shoulder, semi-constrained metal/polymer, cemented, CFR 888.3660
Regulatory Class	II
Predicate Device	Primary - K142863: Arthrex Univers Revers Prosthesis Shoulder System Reference - K053274: Zimmer Anatomical Shoulder System
Purpose of Submission	This **traditional 510(k)** premarket notification is submitted to obtain clearance for the *Arthrex UNIVERS REVERS COATED BASEPLATE*.
Device Description	The Arthrex *UNIVERS REVERS COATED BASEPLATE* is a coated titanium glenoid baseplate designed to be used as the glenoid component of the existing Univers Revers Shoulder Prosthesis System. The baseplate is centrally anchored by a barbed post with superior and inferior multi-directional screws to ensure optimal fixation. The baseplate comes in three sizes and is designed to be paired with the Univers Revers glenosphere.
Indications for Use	The Arthrex UNIVERS REVERS COATED BASEPLATE is designed to be used as the glenoid component of the existing Univers Revers Shoulder Prosthesis System. The Arthrex UNIVERS REVERS 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 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 COATED BASEPLATE is coated and is intended for cementless use with the addition of screws for fixation.
Performance Data	Mechanical testing (Rocking Horse, Shear Force) demonstrated that the Arthrex *UNIVERS REVERS COATED BASEPLATE* 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.

	Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the Arthrex *UNIVERS REVERS COATED BASEPLATE* 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.