March 29, 2018

Arthrex Inc.
David Rogers
Project Manager, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K171841
Trade/Device Name: Arthrex Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD, PHX
Dated: February 26, 2018
Received: March 1, 2018

Dear Mr. Rogers:

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,

Mark N. Melkerson -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171841

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171841

Device Name
Arthrex Univers Revers Shoulder Prosthesis System

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 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 the Arthrex Humeral Suture Cups. 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)

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See PRA Statement below.

510(k) Number *(if known)*
K171841

Device Name
Arthrex Univers Revers CA Heads and Adapters

Indications for Use *(Describe)*
The Arthrex Univers Revers CA Heads 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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171841

Device Name
Arthrex Univers Shoulder Fracture Prosthesis

Indications for Use *(Describe)*
The Arthrex Univers Shoulder Fracture Prosthesis is indicated for severe pain or significant disability resulting from degenerative, rheumatoid, or traumatic disease or injury of the glenohumeral joint. This included traumatic or pathological conditions of the shoulder resulting in fracture of the glenohumeral joint, including impression fractures, comminuted fracture, humeral head fracture, displaced 3-or4-fragment proximal head fractures, avascular necrosis of the humeral head, and fractures of the anatomical neck.

The Arthrex Univers Shoulder Fracture Prosthesis is designed for cemented or non-cemented use. This device may be used for hemi or total shoulder repair, utilizing the appropriate Arthrex Univers Glenoid component, which is to be cemented in place.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171841

Device Name
Arthrex UNIVERS II and UNIVERS APEX Shoulder Prosthesis

Indications for Use *(Describe)*
The Arthrex UNIVERS II and UNIVERS APEX Shoulder Prosthesis is indicated in replacement(s) when conditions including severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, or injury of the glenohumeral joint; non-union humeral head fractures of long duration; irreducible 2- and 4-part proximal humeral fractures; avascular necrosis of the humeral head, or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable.

The glenoid components are intended for cemented fixation in the joint and must only be used with appropriate bone cement.

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)

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510(k) Summary or 510(k) Statement

Date Prepared	March 28, 2017
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	David L Rogers Project Manager, Regulatory Affairs 1-239-643-5553, ext. 71924 david.rogers@arthrex.com
Name of Device	Arthrex Shoulder Systems
Common Name	Shoulder Prosthesis
Product Code	KWS, HSD, PHX
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
Predicate Device	K020345: Arthrex Univers Shoulder Fracture Prosthesis K071032: Arthrex Univers II Shoulder Prosthesis K083435: Arthrex Univers II Pegged Glenoid K103466: Arthrex Univers II #5 Stem K120044: Arthrex Univers II Shoulder Prosthesis – XL Glenoids K130129: Arthrex Univers Revers K130675: Arthrex Univers CA Heads K131633: Arthrex Univers Apex K142863: Arthrex Univers Revers Fracture K151527: Arthrex Univers Revers CA Heads K153115: Arthrex Univers Apex Size 5 Stem K161108: Arthrex VaultLock Glenoid K161782: Arthrex Univers Revers Shoulder Prosthesis System K173271: Arthrex Revers Coated Baseplate
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the modification to the device labeling for the Arthrex Shoulder Systems to include the "MR Conditional" statement in accordance with the FDA Guidance, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment".
Device Description	The Arthrex Shoulder Systems encompass the following FDA cleared devices: • Arthrex Univers II Should Prosthesis • Arthrex Univers Apex • Arthrex Univers Revers Shoulder Prosthesis System These systems are comprised of humeral and glenoid components for use in shoulder prosthesis.
Indications for Use	The **Arthrex Univers Shoulder Fracture Prosthesis** is indicated for severe pain or significant disability resulting from degenerative, rheumatoid, or traumatic disease or injury of the glenohumeral joint. This included traumatic or pathological conditions of the shoulder resulting in fracture of the glenohumeral joint, including impression fractures, comminuted fracture, humeral head fracture, displaced 3-or4-fragment proximal head fractures, avascular necrosis of

the humeral head, and fractures of the anatomical neck.

The Arthrex Univers Shoulder Fracture Prosthesis is designed for cemented or non-cemented use. This device may be used for hemi or total shoulder repair, utilizing the appropriate Arthrex Univers Glenoid component, which is to be cemented in place.

The **Arthrex UNIVERS II** and **UNIVERS APEX** Shoulder Prosthesis is indicated in replacement(s) when conditions including severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, or injury of the glenohumeral joint; non-union humeral head fractures of long duration; irreducible 2- and 4-part proximal humeral fractures; avascular necrosis of the humeral head, or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable.

The glenoid components are intended for cemented fixation in the joint and must only be used with appropriate bone cement.

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 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 the Arthrex Humeral Suture Cups. The glenoid baseplate is CaP coated and is intended for cementless use with the addition of screws for fixation.

The **Arthrex Univers Revers CA Heads 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.

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	Non-clinical testing and in-vivo electromagnetic simulation per the FDA Guidance, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", demonstrated that the Arthrex Shoulder Systems are "MR Conditional". Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Conclusion	The Arthrex Shoulder Systems are 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.