DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 21, 2016

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

Re: K161782
Trade/Device Name: Arthrex Univers Revers Shoulder Prosthesis System
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: Class II
Product Code: HSD, PHX
Dated: October 19, 2016
Received: October 20, 2016

Dear David L. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510K SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	November 21, 2016
Manufacturer/ Distributor/ Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	David L Rogers Project Manager, Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 71924 Fax: 239/598.5508 Email: david.rogers@arthrex.com
Trade Name	***Arthrex Univers Revers Shoulder Prosthesis System***
Common Name	Shoulder Prosthesis
Product Code, Classification Name, CFR	HSD – Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis, CFR 888.3690 PHX – Shoulder joint metal/polymer semi-constrained cemented prosthesis, CFR 888.3660
Predicate Device	*K130129/K142863: Arthrex Univers Revers Shoulder Prosthesis System*
Purpose of Submission	This **traditional 510(k)** premarket notification is submitted to obtain clearance for the Arthrex Univers Revers Humeral Stems and Suture Cups as a line extension to the ***Arthrex Univers Revers Shoulder Prosthesis System***.
Device Description	The Arthrex Univers Revers Humeral Stems and Suture Cups is a line extension to the Arthrex Univers Revers Shoulder Prosthesis System. The proposed humeral stems, sizes 6 thru 15, are modified versions of the humeral stems cleared under K130129/K142863 and are designed to be shorter in medial to lateral width. The line extension also introduces a size 5 modular stem as well as modified versions of the Humeral Suture Cups.
Intended 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 Suture Cups. The glenoid baseplate is CaP coated and is intended for cementless use with the addition of screws for fixation.
Substantial Equivalence Summary	The Arthrex Univers Revers Humeral Stems and Suture Cups are substantially equivalent to the predicate devices, in which the fundamental scientific technology and intended use are the same. Any differences between the Arthrex Univers Revers Humeral Stems and Suture Cups and the predicate are considered minor and do not raise questions concerning safety and effectiveness. Dynamic fatigue testing was performed to evaluate the fatigue resilience of the proposed Univers Revers Humeral Stems and Humeral Suture Cups. All constructs survived 10 million cycles for both compression and torsion loading conditions. Abrasion testing was also performed to assess the risk of suture abrasion using the new Humeral Suture Cups. Abrasion resistance exceeded the predicate. Based on the indication for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the ***Arthrex Univers Revers Shoulder Prosthesis System*** is substantially equivalent to currently marketed predicate device.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K161782

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.

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(Humeral) Stems are intended for cemented or cementless applications for use with 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.