DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 25, 2014

Arthrex, Incorporated
Ms. Courtney Smith
Regulatory Affairs Manager
1370 Creekside Boulevard
Naples, Florida 34108

Re: K142863
Trade/Device Name: Universe Revers Shoulder Prosthesis System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: September 30, 2014
Received: October 1, 2014

Dear Ms. 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.

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" (21CFR 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 yours,

Lori A. Wiggins -S

for

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

Enclosure

2.3 INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K142863

Device Name

Universe 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 System 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. 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FORM FDA 3881 (9/13)

PSC Publishing Services (301) 443-6740 EF

510(k) Summary of Safety and Effectiveness

Date Summary Prepared	November 24, 2014
Manufacturer/Distributor/Sponsor	Arthrex, Inc 1370 Creekside Blvd. Naples, FL
510(k) Contact	Courtney Smith Regulatory Affairs Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: csmith@arthrex.com
Trade Name	***Univers Revers Shoulder Prosthesis System***
Common Name	Shoulder Prosthesis
Product Code – Classification Name CFR	**PHX** – Shoulder joint metal/polymer semi-constrained cemented prosthesis, CFR 888.3660
Predicate Device	K053274: Zimmer Anatomical Shoulder System K130129: Arthrex Univers Revers Prosthesis Shoulder System
Purpose of Submission	This **traditional 510(k)** premarket notification is submitted to include a fracture indication for the Univers Revers Shoulder Prosthesis System
Device Description	The Arthrex Univers Revers Shoulder Prosthesis System has an articular design that is inverted compared to traditional total shoulder prosthesis. The system is comprised of two main components; the Arthrex Univers Revers Shoulder Prosthesis and the Universal Glenoid Shoulder Prosthesis. The Arthrex Univers Revers Shoulder Prosthesis is a titanium humeral stem and epiphysis or humeral cup, a titanium spacer, and an UHMWPE humeral cup liner. The humeral stem and epiphysis are available uncoated or with CaP coating. The Universal Glenoid Shoulder Prosthesis consists of a TPS/CaP coated titanium glenoid baseplate, a cobalt chrome glenosphere, and titanium screws.
Intended Use	The Univers Revers Shoulder Prosthesis 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. The glenoid baseplate is CaP coated and is intended for cementless use with the addition of screws for fixation.
Substantial Equivalence Summary	The Univers Revers Shoulder Prosthesis System is substantially equivalent to the predicate devices in which the basic features and intended uses are the same. Any differences between the Univers Revers Shoulder Prosthesis System and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The proposed shoulder devices are substantially equivalent to the predicate devices in regards to its intended use, design, size ranges, and materials. Mechanical testing of the Univers Revers Shoulder Prosthesis System was conducted and the results of this testing was compared to both the Zimmer Anatomical Revers Shoulder System and the Tornier Aequalis in K130129. No significant changes have been made to the Univers Revers Shoulder Prosthesis System, which would affect performance of the device. The Zimmer Anatomical Revers Shoulder System (K053274) is cleared with the fracture indication; therefore no further performance testing is necessary to add the fracture indication to the Univers Revers Shoulder Prosthesis System. Additional Performance testing, animal studies and clinical data and conclusions are not needed for this device. Based on the indication for use, technological characteristics, and the comparison to the predicate devices, Arthrex, Inc. has determined that the Univers Revers Shoulder Prosthesis System is substantially equivalent to currently marketed predicate devices.