



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

December 14, 2017

Re: K170414

Trade/Device Name: Arthrex Univers Revers Apex Humeral Stems
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: October 30, 2017
Received: December 5, 2017

Dear David 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
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Summary

Date Prepared	December 12, 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 Univers Revers Apex Humeral Stems
Common Name	Shoulder Prosthesis
Product Code	PHX
Classification Name	21 CFR 888.3660
Regulatory Class	II
Predicate Device	K161782: Arthrex Univers Revers Shoulder Prosthesis System
Reference Predicate	K122698: Tornier Ascend Flex Prosthesis
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Univers Revers Apex Humeral Stems as a line extension to the Arthrex Univers Revers Humeral Stems cleared under K161782 for use in the Arthrex Univers Revers Shoulder Prosthesis System.
Device Description	The Arthrex Univers Revers Apex Humeral Stems are Titanium humeral stems with a Calcium Phosphate coating designed to articulate with the Arthrex Univers Revers Shoulder Prosthesis System. The stem will be offered sterile in 10 sizes (Size 6-15). The primary differences between the Arthrex Univers Revers Apex Humeral Stem and the predicate device are that the proposed device is shorter in superior to inferior length and contains two suture holes.
Indications for Use	<p>The Univers Revers Shoulder Prosthesis System is indicated for use in a grossly rotator cuff deficient glenohumeral joint with severe arthropathy. 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.</p> <p>The Univers Revers Shoulder Prosthesis System is indicated for primary total shoulder replacement for the relief of pain and significant disability due to rotator cuff deficiency.</p> <p>(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.</p>
Performance Data	<p>Dynamic fatigue testing was performed to evaluate the fatigue resilience of the proposed stems. All constructs survived 10 million cycles for both compression and torsion loading conditions.</p> <p>An engineering analysis was conducted in evaluating stem fixation.</p> <p>Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.</p>
Conclusion	The Arthrex Univers Revers Apex Humeral Stem is 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

Indications for Use

510(k) Number (if known)

K170414

Device Name

Arthrex Univers Revers Apex Humeral Stems

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. 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 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.

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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