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

April 19, 2016

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

Re: K151527
Trade/Device Name: Arthrex Univers Revers CA Heads and Adapters
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: March 9, 2016
Received: March 11, 2016

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 Parts 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,

Mark N. Melkerson -S

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

Enclosure

1.1 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)*

K151527

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)

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)*

1.1 510K SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	April 12, 2016
Manufacturer/ Distributor/ Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Courtney Smith Manager, Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext.71720 Fax: 239/598.5508 Email: Courtney.Smith@Arthrex.com
Trade Name	***Arthrex Univers Revers CA Heads and Adapters***
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	Primary Predicate K130675: *Arthrex Univers II CA Heads* Reference Predicates: K130129 / 142863: *Arthrex Univers Revers Prosthesis Shoulder System*
Purpose of Submission	This traditional 510(k) premarket notification is submitted to obtain clearance for a line extension to the *Arthrex Univers Revers Shoulder Prosthesis System.*
Device Description	The ***Arthrex Univers Revers CA Heads and Adapters*** consist of a line of CA Heads and Adapters which are designed to be used with the existing well-fixated Revers stem of the Univers Revers Shoulder Prosthesis System (K130129 and K142863). The ***Arthrex Univers Revers CA Heads and Adapters*** will convert existing reversed shoulder prosthesis to a hemi anatomic configuration. The cobalt chrome CA Head were designed with a larger area of articulation to allow for articulation with the acromion in patients with gross rotator cuff deficiency, similar to the Univers II CA Heads (K130675). The proposed ***Arthrex Univers Revers CA Heads*** have a similar spherical articulating surface as that of the previously cleared heads and are available in 14 nominal sizes. The Adapters are manufactured from Titanium and UHMWPE and are available in 3 nominal sizes.

Intended Use	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
Substantial Equivalence Summary	The ***Arthrex Univers Revers CA Heads and Adapters*** is substantially equivalent to the predicate devices in which the basic design features and intended uses are the same. Any differences between the ***Arthrex Univers Revers CA Heads and Adapters*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The proposed devices are substantially equivalent to the predicate devices in regards to its intended use, design, size range, and material. The ***Arthrex Univers Revers CA Heads and Adapters*** will convert existing reversed shoulder prosthesis to a hemi anatomic configuration. The cobalt chrome CA Heads are available in 14 nominal sizes, and were designed with a larger area of articulation to allow for articulation with the acromion in patients with gross rotator cuff deficiency, similar to the Univers II CA Heads (K130675). The Adapters are manufactured from Titanium and UHMWPE and are available in 3 nominal sizes. The submitted in-vitro testing (static loading, endurance, fretting corrosion, disengagement, torque out) demonstrate that the performance of the proposed devices is substantially equivalent to that of the predicate devices. The mechanical data indicate that the ***Arthrex Univers Revers CA Heads and Adapters*** are adequate for their intended use. Clinical data and conclusions are not needed for this device. Based on the indication for use, technological characteristics, and the comparison to the predicate device, Arthrex, Inc. has determined that the ***Arthrex Univers Revers CA Heads and Adapters*** are substantially equivalent to currently marketed predicate devices.