



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

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

November 23, 2015

Re: K153115

Trade/Device Name: Arthrex Unipers Apex, Size 5 Stem  
Regulation Number: 21 CFR 888.3660  
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis  
Regulatory Class: Class II  
Product Code: KWS, HSD  
Dated: October 26, 2015  
Received: October 28, 2015

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

Enclosure

**2.5 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)

**K153115**

Device Name

***Arthrex Univers Apex, Size 5 Stem***

Indications for Use (Describe)

The ***Arthrex Univers Apex, Size 5 Stem*** is indicated for:

The Arthrex Univers Apex is indicated in replacements(s) when conditions include 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 designed for cemented fixation in the joint and must only be used with an 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)

**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)

## 2.6 510K SUMMARY OF SAFETY AND EFFECTIVENESS

<b>Date Summary Prepared</b>	October 22, 2015
<b>Manufacturer/ Distributor/ Sponsor</b>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<b>510(k) Contact</b>	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
<b>Trade Name</b>	<b>Arthrex Univers Apex, Size 5 Stem</b>
<b>Common Name</b>	Shoulder Prosthesis
<b>Product Code, Classification Name, CFR</b>	<b>KWS</b> – Prosthesis, Shoulder, semi-constrained metal/polymer, cemented, CFR 888.3660 <b>HSD</b> – Prosthesis, Shoulder, Hemi-Humeral, Metal, Uncemented, CFR 888.3690
<b>Predicate Device</b>	K131633: <i>Arthrex Univers Apex Stems</i> K103466: <i>Arthrex Size 5 Univers II Stems</i>
<b>Purpose of Submission</b>	This special 510(k) premarket notification is submitted to obtain clearance for a line extension to the <i>Arthrex Univers Apex Stems</i> .
<b>Device Description</b>	The <b>Arthrex Univers Apex, Size 5 Stem</b> , subject to this submission, is a smaller version of the previously cleared Arthrex Univers Apex (K131633). It is a modular stem with fixed inclination angle design and is the identical size as the previously cleared Size 5 Univers II stems (K103466). The stem is machined of titanium alloy. The distal section of the stem has a conical design. The proximal section of the stem is rectangular in design and has a morse-taper for the mating of humeral heads. The stem's surface finish is textured for cemented or press-fit (non-cemented) implantation. The <b>Arthrex Univers Apex, Size 5 Stem</b> falls within the length range of the previously cleared Univers Apex stems (K131633).
<b>Intended Use</b>	The Arthrex Univers Apex is indicated in replacements(s) when conditions include 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 designed for cemented fixation in the joint and must only be used with an appropriate bone cement.
<b>Substantial</b>	The <b>Arthrex Univers Apex, Size 5 Stem</b> is substantially equivalent to the predicate

**Equivalence Summary**

devices in which the basic design features and intended uses are the same. Any differences between the **Arthrex Univers Apex, Size 5 Stem** 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 submitted in-vitro testing (cyclic compression loading) The submitted mechanical testing data demonstrated that the performance of the proposed devices is substantially equivalent to that of the predicate devices. The mechanical data indicate that the **Arthrex Univers Apex, Size 5 Stem** is 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 Apex, Size 5 Stem** is substantially equivalent to currently marketed predicate devices.

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