March 8, 2019

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

Re: K182799
Trade/Device Name: Arthrex Univers II Shoulder Prosthesis System: Titanium Humeral Heads
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: February 13, 2019
Received: February 14, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Michael C. Owens -S
Digitally signed by Michael C. Owens -S
Date: 2019.03.08 14:33:07 -05'00'

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

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

510(k) Number *(if known)*
K182799

Device Name
Arthrex Univers II Shoulder Prosthesis System: Titanium Humeral Heads

Indications for Use *(Describe)*
The Arthrex UNIVERS II Shoulder Prosthesis is indicated in replacement(s) when conditions including 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 intended for cemented fixation in the joint and must only be used with appropriate bone cement.

The Arthrex Titanium Humeral Head is indicated for patients with suspected cobalt alloy sensitivity. The wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy. A Titanium humeral head is not recommended for patients who lack suspected material sensitivity to cobalt alloy.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

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| ***Date Prepared*** | December 31, 2018 |
| ***Submitter*** | Arthrex Inc.<br>1370 Creekside Boulevard<br>Naples, FL 34108-1945 |
| ***Contact Person*** | David L Rogers<br>Project Manager, Regulatory Affairs<br>1-239-643-5553, ext. 71924<br>david.rogers@arthrex.com |
| ***Name of Device*** | Arthrex Univers II Shoulder Prosthesis System: Titanium Humeral Heads |
| ***Common Name*** | Shoulder Prosthesis |
| ***Product Code*** | KWS |
| ***Classification Name*** | 21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis |
| ***Regulatory Class*** | II |
| ***Predicate Device*** | K140390: Titanium Versa-Dial Humeral Head Prosthesis<br>K140082: Aequalis Ascend Flex Shoulder System<br>K071032: Arthrex Univers II Shoulder Prosthesis |
| ***Purpose of Submission*** | This Traditional 510(k) premarket notification is submitted to add a line extension of titanium humeral heads to the Arthrex Univers II shoulder prosthesis system cleared under K071032. |
| ***Device Description*** | The Titanium humeral heads are intended to be used in the Arthrex Univers II Shoulder Prosthesis System. The humeral heads were originally cleared under predicate K071032 as cobalt-chromium (CoCr) devices. The design of the titanium humeral heads is identical to the CoCr heads cleared under predicate K071032. The only difference between the proposed device and the predicate is the material. The titanium humeral heads will provide an alternative to CoCr for use on patients with nickel allergies. |
| ***Indications for Use*** | The Arthrex UNIVERS II Shoulder Prosthesis is indicated in replacement(s) when conditions including 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.<br><br>The glenoid components are intended for cemented fixation in the joint and must only be used with appropriate bone cement.<br><br>The Arthrex Titanium Humeral Head is indicated for patients with suspected cobalt alloy sensitivity. The wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy. A Titanium humeral head is not recommended for patients who lack suspected material sensitivity to cobalt alloy. |
| ***Performance Data*** | Fatigue testing, pull-off testing, and wear testing were conducted to evaluate the strength and fatigue properties of the proposed titanium humeral heads. |

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| | Additionally, an engineering analysis was performed to address the substantial equivalence of hardness, adhesion, surface roughness, scratch resistance, young's modulus, and articulating congruency compared to the predicate device.<br><br>Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications. |
| ***Conclusion*** | The Arthrex Univers II Shoulder Prosthesis Titanium Humeral Heads are 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.<br><br>Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the Arthrex Univers II Shoulder Prosthesis Titanium Humeral Heads is substantially equivalent to the currently marketed predicate device. |