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

December 21, 2018

Re: K181555
Trade/Device Name: Arthrex Fracture Adapter Hemi Shoulder Prosthesis
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: November 19, 2018
Received: November 20, 2018

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,

Daniel S. Ramsey -S
2018.12.21 16:10:24 -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)*
K181555

Device Name
Arthrex Fracture Adapter Hemi Shoulder Prosthesis

Indications for Use *(Describe)*
The Arthrex Fracture Adapter Hemi Shoulder Prosthesis is indicated for severe pain or significant disability resulting from degenerative, rheumatoid, or traumatic disease or injury of the glenohumeral joint. This includes traumatic or pathological conditions of the shoulder resulting in fracture of the glenohumeral joint, including impression fractures, comminuted fracture, humeral head fracture, displaced 3-or-4-fragment proximal head fractures, avascular necrosis of the humeral head, and fractures of the anatomical neck.

The Arthrex Fracture Adapter Hemi Shoulder Prosthesis is for uncemented use. The device may be used for hemi or total shoulder repair, utilizing the appropriate Arthrex Univers Glenoid component, which is to be cemented in place.

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.

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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 or 510(k) Statement

Date Prepared	December 20, 2018
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	David L Rogers Regional Manager, Regulatory Affairs 1-239-643-5553, ext. 71924 david.rogers@arthrex.com
Name of Device	Arthrex Fracture Adapter Hemi Shoulder Prosthesis
Common Name	Shoulder Prosthesis
Product Code	KWS, HSD
Classification Name	21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class	II
Predicate Device	K020345: Arthrex Univers Fracture Prosthesis K071032: Arthrex Univers II Shoulder Prosthesis K130129/K142863: Arthrex Univers Revers Shoulder Prosthesis System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for a product line of fracture adapters to be used with FDA cleared Arthrex humeral stems and heads for anatomic hemi shoulder prosthesis.
Device Description	The fracture adapters are manufactured from Titanium with a hydroxyapatite (HA) coating and are offered in 10 sizes. The Fracture Adapters mate with a trunnion and FDA cleared Arthrex Humeral Stems and Heads for anatomic hemi shoulder prosthesis.
Indications for Use	The **Arthrex Fracture Adapter Hemi Shoulder Prosthesis** is indicated for severe pain or significant disability resulting from degenerative, rheumatoid, or traumatic disease or injury of the glenohumeral joint. This includes traumatic or pathological conditions of the shoulder resulting in fracture of the glenohumeral joint, including impression fractures, comminuted fracture, humeral head fracture, displaced 3-or-4-fragment proximal head fractures, avascular necrosis of the humeral head, and fractures of the anatomical neck. The Arthrex Fracture Adapter Hemi Shoulder Prosthesis is for uncemented use. The device may be used for hemi or total shoulder repair, utilizing the appropriate Arthrex Univers Glenoid component, which is to be cemented in place.
Performance Data	Dynamic fatigue testing was performed to evaluate the fatigue resilience of the proposed construct. The testing demonstrates that the fatigue strength of the proposed devices meets the same acceptance criteria as the predicate device for the desired indications. Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Conclusion	The Arthrex Fracture Adapter Hemi Shoulder Prosthesis 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.