DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 29, 2016

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

Re: K161108
Trade/Device Name: Arthrex VaultLock Glenoid
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: August 8, 2016
Received: August 9, 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K161108

Device Name
Arthrex VaultLock Glenoid

Indications for Use *(Describe)*

The Arthrex VaultLock Glenoid 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)*

[X] 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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1.1 510K SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	August 22, 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 VaultLock Glenoid***
Common Name	Shoulder Prosthesis
Product Code, Classification Name, CFR	**KWS** – Prosthesis, Shoulder, semi-constrained metal/polymer, cemented, CFR 888.3660
Predicate Device	*Primary Predicate* Arthrex Univers II Shoulder System – Pegged Glenoid, *K083435* *Reference Predicate* Arthrex Univers II XL Pegged Glenoids - *K120044*
Purpose of Submission	This special 510(k) premarket notification is submitted to obtain clearance for the ***Arthrex VaultLock Glenoid***
Device Description	The ***Arthrex VaultLock Glenoid*** is a UHMWPE glenoid designed to be used with the existing Univers II Shoulder Prosthesis system (K071032). The proposed ***Arthrex VaultLock Glenoid*** has an identical spherical articulating surface as that of the previously cleared glenoids and is available in 4 nominal sizes.
Intended Use	The ***Arthrex VaultLock Glenoid*** 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 appropriate bone cement.
Performance	• Bacterial endotoxin testing per EP 2.6.14/USP <85>. • Preclinical testing performed per ASTM F2028 (Rocking horse stability).
Conclusion	The ***Arthrex VaultLock Glenoid*** is substantially equivalent to the predicate devices in which the basic design features and intended uses are the same. Any differences between the ***Arthrex VaultLock Glenoid*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness.