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

November 17, 2021

Re: K212415
Trade/Device Name: Arthrex Modular Glenoid System - Titanium Glenosphere
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: November 2, 2021
Received: November 4, 2021

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Jiping Chen, Ph.D., M.P.H.
Acting Division Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212415

Device Name
Arthrex Modular Glenoid System - Titanium Glenosphere

Indications for Use *(Describe)*
The Arthrex Univers Revers Modular Glenoid System is indicated for use in a grossly rotator cuff deficient glenohumeral joint with severe arthropathy or a previously failed joint replacement with a gross rotator cuff deficiency. 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.

The Arthrex Univers Revers Modular Glenoid System is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

The Arthrex Univers Revers Modular Glenoid System is porous coated and is intended for cementless use with the addition of screws for fixation.

The Arthrex Titanium Glenospheres are 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 glenosphere 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

1. 510(k) Summary

Date Prepared	November 17, 2021
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Ivette Galmez Principal Specialist, Regulatory Affairs 1-239-643-5553 ivette.galmez@arthrex.com
Name of Device	Arthrex Modular Glenoid System - Titanium Glenosphere
Common Name	Shoulder Prosthesis
Product Code	PHX
Classification Name	21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class	Class II
Predicate Device	K173900: Arthrex Modular Glenoid System
Reference Device	K182799: Arthrex Univers II Shoulder Prosthesis System: Titanium Humeral Heads K203100: Arthrex Eclipse Titanium Humeral Head
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain FDA clearance for a line extension of a Titanium Glenosphere for the Arthrex Modular Glenoid System cleared under K173900.
Device Description	The proposed Titanium Glenosphere is manufactured from Ti-6Al-4V ELI per ASTM F136 and will be offered in sizes ranging from 33-42mm. The Titanium Glenospheres are intended to be used with the same components as originally cleared under K173900. The proposed Titanium Glenosphere share the same dimensional specifications to the cleared CoCr Glenospheres (K173900).
Indications for Use	The Arthrex Univers Revers Modular Glenoid System is indicated for use in a grossly rotator cuff deficient glenohumeral joint with severe arthropathy or a previously failed joint replacement with a gross rotator cuff deficiency. 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. The Arthrex Univers Revers Modular Glenoid System is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. The Arthrex Univers Revers Modular Glenoid System is porous coated and is intended for cementless use with the addition of screws for fixation. The Arthrex Titanium Glenospheres are 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 glenosphere is not recommended for patients who lack suspected material sensitivity to cobalt alloy.
Performance Data	Fatigue testing and push-out testing were conducted to evaluate the fatigue properties and disassembly force of the Arthrex Titanium Glenosphere. Additionally, an engineering analysis was performed to address the substantial equivalence of hardness, adhesion, surface roughness, scratch resistance, and young's modulus compared to the predicate device. Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Conclusion	The Arthrex Titanium Glenosphere has the same intended use and the same fundamental scientific technology as the Arthrex Modular Glenoid System. Based on the non-clinical data presented in this 510(k), Arthrex concludes that the proposed device is substantially equivalent to the currently marketed predicate device.