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

November 20, 2020

Re: K203100
Trade/Device Name: Arthrex Eclipse Titanium Humeral Head
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: QHQ, PKC
Dated: October 12, 2020
Received: October 14, 2020

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 Michael Owens
Assistant 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203100

Device Name
Arthrex Eclipse Titanium Humeral Head

Indications for Use *(Describe)*
The Arthrex Eclipse Shoulder Prosthesis is indicated for severely painful and/or disabled joint resulting from osteoarthritis or traumatic arthritis. The humeral component is fixated with a hollow screw and the glenoid components are intended for cemented fixation in the joint and must only be used with appropriate bone cement.

The Arthrex Eclipse 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.

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510(k) Summary

Date Prepared	November 19, 2020
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	David L Rogers Senior Manager, Regulatory Affairs 1-239-643-5553 david.rogers@arthrex.com
Name of Device	Arthrex Eclipse Titanium Humeral Head
Common Name	Shoulder Prosthesis
Product Code	PKC, QHQ
Classification Name	21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class	Class II
Predicate Device	K201542: Arthrex Eclipse Shoulder Prosthesis
Reference Device	K182799: Arthrex Univers II Shoulder Prosthesis System: Titanium Humeral Heads K183194: Arthrex Eclipse Shoulder Prosthesis
Device Description	The proposed Eclipse Titanium humeral head is manufactured from Ti-6Al-4V ELI per ASTM F136 and is offered in sizes ranging from 37-55mm with varying offsets of 16-23mm. The humeral head is placed on a trunnion, which is fixated to the proximal humerus by a hollow screw. The Titanium humeral heads are used with the existing trunnions and hollow screws cleared under the predicate.
Technological Characteristics	The Arthrex Eclipse Titanium Humeral Head is a Titanium version of the Arthrex Eclipse Cobalt Chromium Humeral Head cleared under K201542/K183194. Compared to the predicate, the proposed Titanium Humeral Heads have the same fundamental scientific technology, engineering design, sterilization, packaging configuration, and shelf-life. The size ranges of the subject device are the same as originally cleared under K201542/K183194. The difference is that the subject device is manufactured from Titanium as opposed to Cobalt Chromium and the indications for use has been updated to explain that the wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy and that Titanium humeral heads are not recommended for patients who lack suspected material sensitivity to cobalt alloy.
Indications for Use	The Arthrex Eclipse Shoulder Prosthesis is indicated for severely painful and/or disabled joint resulting from osteoarthritis or traumatic arthritis. The humeral component is fixated with a hollow screw and the glenoid components are intended for cemented fixation in the joint and must only be used with appropriate bone cement. The Arthrex Eclipse 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 and Pull Off testing was performed to evaluate the fatigue properties of the Arthrex Eclipse Titanium Humeral Head. 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. An engineering analysis was performed to ensure that the subject device is not a new worst-case regarding MRI force, torque, and image artifact and can be labeled MR Conditional in accordance with the FDA guidance Testing and Labeling Medical Devices in the Magnetic Resonance (MR) Environment.

Conclusion	The Arthrex Eclipse Titanium Humeral Head has the same intended use and the same fundamental scientific technology as the Arthrex Eclipse Shoulder Prosthesis 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.