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

July 8, 2020

Re: K201542
Trade/Device Name: Arthrex Eclipse Shoulder Prosthesis System
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: June 5, 2020
Received: June 9, 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
Acting 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)*

K201542

Device Name
Arthrex Eclipse Shoulder Prosthesis System

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.

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	July 8, 2020
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	David L Rogers Manager, Regulatory Affairs 1-239-643-5553 david.rogers@arthrex.com
Name of Device	Arthrex Eclipse Shoulder Prosthesis System
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	K183194: Arthrex Eclipse Shoulder Prosthesis
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain FDA clearance for a size 37 Humeral Head and Trunnion as a line extension to the Arthrex Eclipse Shoulder Prosthesis System cleared under K183194.
Device Description	The proposed size 37 humeral head is manufactured from Cobalt Chromium (CoCr) and will be offered with a 16mm offset. The proposed size 37 trunnion is manufactured from Titanium alloy (Ti6Al4V) with its underside coated with a Titanium Plasma Spray (TPS) coating. The trunnion will be offered in a slotted design. The Size 37 Head and Trunnion will be used with the existing hollow screws cleared under the predicate.
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.
Performance Data	Static and dynamic compression testing presented in the predicate 510(k) clearance is leveraged to demonstrate the fatigue resilience of the proposed Arthrex Eclipse Shoulder Prosthesis.
Conclusion	The Arthrex Eclipse Size 37 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.