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

July 26, 2019

Re: K183194
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 25, 2019
Received: June 26, 2019

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,

Daniel S. Ramsey -S
2019.07.26 14:49:02 -04'00'

FOR CAPT Raquel Peat, PhD, MPH, USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) Summary

Date Prepared
July 26, 2019

Submitter
Arthrex Inc.
1370 Creekside Boulevard
Naples, FL 34108-1945

Contact Person
David L Rogers
Manager, Regulatory Affairs
1-239-643-5553, ext. 71924
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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
II

Primary Predicate Device
K071032: Arthrex Univers II Shoulder Prosthesis
K171858: Sidus Stem-Free Shoulder
K143552: Simpliciti Shoulder System

Reference Predicate Device
K173388: Exactech Equinox

Purpose of Submission
This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Eclipse Shoulder Prosthesis.

Device Description
The Arthrex Eclipse Shoulder Prosthesis is a stemless humeral joint (hemi-shoulder) prosthesis that is designed as a humeral head replacement device. It consists of a humeral head; a trunnion; and a hollow screw. The Arthrex Eclipse Shoulder Prosthesis System replaces the proximal humeral bone, including the articulating surface, using an

anatomical reconstruction surgical technique. The Eclipse fixates to the humeral bone by a hollow screw that is torqued into place.

The humeral head is manufactured from Cobalt Chromium (CoCr) and is offered in 10 sizes (39-55mm) with varying offsets of 16-23mm. The trunnion is manufactured from Titanium alloy (Ti6Al4V) with a titanium plasma spray (TPS) Calcium Phosphate (CaP) coating and is available in 10 sizes (37-55mm). The hollow screw is manufactured from Titanium alloy (Ti6Al4V) and is offered in 4 sizes (30-45mm).

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.

Summary of Technological Characteristics

The Arthrex Eclipse Shoulder Prosthesis System has the same intended use as the primary predicate devices. The technological characteristics (material, sizing, indications, coating, packaging, shelf-life, and sterilization) of the Arthrex Eclipse Shoulder Prosthesis System are substantially equivalent to the predicate devices. The design differences have been demonstrated through clinical and non-clinical performance data and do not raise new issues of safety or effectiveness.

The primary difference between the Arthrex Eclipse Shoulder Prosthesis System and the predicate Arthrex Univers II is that the Eclipse is a stemless prosthesis as opposed to a stem design. However, the Arthrex Eclipse is similar to other legally marketed stemless shoulder devices, such as the Sidus Stem-Free Shoulder and the Simpliciti Shoulder System. The primary difference between the Arthrex Eclipse and the stemless predicate devices is the fixation of the humeral component. The Arthrex Eclipse achieves humeral fixation by torqueing the humeral hollow screw component into the humeral bone whereas the stemless predicate devices are fixate by press-fit designs. The table below summarizes the technological characteristics of the Arthrex Eclipse and the predicate devices.

	Arthrex Eclipse (This Submission)	***Arthrex Univers II (K071032)***	***Sidus Stem-Free Shoulder (K171858)***	***Simpliciti Shoulder System (K143552)***
Material	Cobalt Chromium Titanium	Cobalt Chromium Titanium	similar	similar
Head Size range	39-55mm	40-56mm	similar	similar
Humeral component size range	30-45mm	115-151mm	similar	similar
Fixation Method	Screw/Torque	Press Fit	Press Fit	Press Fit
Sterility	Gamma Irradiation	similar	similar	similar
Single Use	Yes	Yes	Yes	Yes
Intended Use	Total Arthroplasty of the Shoulder	Total Arthroplasty of the Shoulder	Total Arthroplasty of the Shoulder	Total Arthroplasty of the Shoulder

Nonclinical Performance Data

Static and dynamic compression testing was performed to evaluate the fatigue resilience of the proposed Arthrex Eclipse Shoulder Prosthesis. The testing demonstrates that the fatigue strength of the proposed devices meets the same acceptance criteria as the predicate device for the desired indications.

A review of clinical literature on the Arthrex Eclipse, which reports on clinical effectiveness outcomes (i.e., Constant Score, Oxford Shoulder Score, range of motion), radiographic findings, and clinical safety outcomes.

Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.

Clinical Performance Data

Level of Evidence & Location of Study

A pivotal study was held in the United States as a prospective, randomized, multi-center study to evaluate the safety and effectiveness of the Arthrex Eclipse Shoulder Prosthesis compared to the Univers II Shoulder Prosthesis (conventional stemmed shoulder) for the treatment of degenerative joint disease in subjects who are candidates for total shoulder replacement.

Primary Composite Endpoint

To be considered a success, the Eclipse subject must meet the following composite clinical success criteria:

- An improvement in the Adjusted Constant Score (for pain, function, and range of motion) from baseline (pre-op) to the Month 24 time-point that is ≥10 points and a final Adjusted Constant Score ≥54.
- Radiographic success at the Month 24 time-point which is defined as absence of clinically significant humeral radiolucency, humeral migration/subsidence (relative to 3 month time point), glenoid migration/subsidence (relative to 3 month time point), device disassembly or fracture, and/or periprosthetic fracture, as described in the radiographic protocol.
- No reoperation, removal, or modification of any study component up to the subject's completion of the study.
- No serious device-related complications up to the subject's completion of the study.

For the composite clinical success measurement using subjects with complete data at Month 24, the success rate was 92.3% for the Eclipse group compared with 89.7% for the Univers II group. The difference between Eclipse and Univers II was 2.6%. The lower-bound of the 1-sided 95% confidence interval for the group difference was -4.5%. The data presented in the table below demonstrate the non-inferiority of the Eclipse subjects to the Univers II control subjects in the overall primary endpoint.

Eclipse			Univers II			Dif	95%	98.131%
Population Size	Sample Size	Success Rate	Population Size	Sample Size	Success Rate	%	1-sided LB	1-sided LB
143	132	92.3%	68	61	89.7%	2.6%	-4.5%	-6.4%

Using the O'Brien-Fleming method to correct for interim analyses, the lower-bound of the 1-sided 98.131% confidence interval for the group difference was -6.4%. Since both -4.5% and -6.4% are greater than -10%, the results from this comparison demonstrate that the study success criterion for non-inferiority has been achieved, even when utilizing a strict success criterion adjusting for interim analyses.

Primary Effectiveness Endpoint

Adjusted Constant Score: 97.1% of Eclipse subjects experienced a clinically meaningful improvement from baseline (defined as a ≥10 point increase and score value ≥54) at Month 24 compared to 92.5% of Univers II subjects.

Secondary effectiveness endpoints measuring pain, function, and overall quality of life demonstrate that a large percentage of Eclipse subjects achieve a clinically significant improvement at 3 months that persists to 24 months following surgery, in similar rates as the Univers II subjects.

Safety

A Kaplan-Meier approach was utilized for subjects who were considered SSI failures per the primary endpoint (n=7 Eclipse and n=2 Univers II). The rate of subsequent surgical intervention was 3.6% for Eclipse subjects and 3.1% for the control subjects through 24 months. In the Eclipse group, two subjects required surgery due to confirmed or

suspected infection; three subjects required revision due to torn rotator cuff or subscapularis tendon; and two subjects required revision due to injury to the shoulder sustained from a fall. In the Univers II group, two subjects required revision due to torn rotator cuff or subscapularis tendon; and one had a reoperation adjacent to the joint (distal clavicle resection) due to pain.

The rate of events that were considered device-related was similar between the two groups (Eclipse: 1.4% vs Univers II: 1.3%). The rate of events that were considered procedure-related was also similar between the two groups (Eclipse: 23.2% vs Univers II: 20.5%).

The Eclipse patients did not experience any radiographic failures and had a higher adjusted Constant Score in comparison to the control.

Significant Findings
Glenoid lucencies were reviewed for Eclipse and Univers II subjects in this study with particular attention to the radiolucency grades observed. At Month 24, the majority of subjects had no glenoid radiolucencies (Grade 0) or minor radiolucencies (Grades 1, 2). A very small percentage of subjects had glenoid radiolucencies ≤2 mm wide (Grade 3) around two or more pegs or around the keel, as applicable. No subjects had glenoid radiolucencies >2 mm wide (Grade 4) or gross loosening (Grade 5). For the subjects with Grade 3 glenoid radiolucencies, the difference in proportions between the control and investigational groups was not significant for either fixation type.

Rotator Cuff tears were observed in both Eclipse and Univers II groups. However, the rates were low (2.3% Eclipse and 1.4% Univers II). Rotator cuff deficiencies are not typically device related and there are no differences in surgical exposure with the Eclipse compared to stemmed arthroplasties or other stemless systems.

Summary
Based on the clinical performance as documented in the pivotal clinical study, the Arthrex Eclipse Shoulder Prosthesis System was found to have a safety and effectiveness profile that is similar to the predicate device.

Literature Review

A total of 298 unique publications were screened and reviewed during the time frame searched (01 January 2008 to 22 May 2019). From this list, abstracts were reviewed and publications excluded if they were not publications focused on clinical experience of the subject device. When needed, the full text was obtained for more in-depth evaluation for possible contribution in providing supportive data for the effectiveness and/or the safety of the subject device used as intended, whether it contained favorable or unfavorable findings.

In total, nine studies were included, reporting on 748 shoulders treated with the ECLIPSE Shoulder Prosthesis. The reviewed literature shows the device is effective and safe when used as intended.

The authors collected relevant information related to the effectiveness and safety of the device. Five studies reported the same pain score measure of the Constant Score and consistently demonstrated a successful reduction in pain and return to activities of daily living. One additional article used an alternative patient reported outcome measure and found the device to be effective in improvement of patient function. All authors who reported effectiveness data reached favorable conclusions for the use of the ECLIPSE device.

While radiographic findings were commonly reported, the majority did not correlate with clinical results (e.g., decline in function or reported adverse event), and a large number were associated with the glenoid component. Heuberer, et al. (2018 mixed cohort) reported radiological changes in 37.0% of patients, i.e., partial osteolysis in approximately 6.9% of patients and complete osteolysis in one or more zones in approximately 30.1% of patients. While there were a large number of radiographic changes noted by the radiologist, these findings did not represent an increased chance of revision surgery or in the patient's clinical outcome (e.g., Constant Score). Additionally, at mid-term follow-up, 96.2% of patients were very satisfied or satisfied with their ECLIPSE. Hawi, et al. (2017 mixed cohort) reported incomplete radiolucency < 1mm in 2.3% of shoulders on the humeral side and an

incomplete radiolucent line was observed in 27.3% of shoulders on the glenoid side. There were no instances of loosening on the humeral or glenoid side and only 1 instance of secondary glenoid wear on the glenoid side. It is important to note that these findings are through 9 years of follow-up, and the authors hypothesize the changes may be due to age-related osteopenia. Authors consistently reported findings were comparable to other literature studies, and possibly attributable to age-related comorbidities. It should also be noted that there is a limitation with radiographic findings reported across literature studies due to the varying definitions used to define radiographic changes, as well as the quality and consistency of the images used.

All clinical complications were consistent with those anticipated for a shoulder arthroplasty patient population. Higher rates were reported for loosening (10.0%), infection (9.8%), rotator cuff deficiency / tear (12%), and secondary glenoid erosion (11.0%). The 10% loosening was reported in two out of 20 patients and specific to the glenoid component. Rotator cuff deficiency / tear was reported at a rate of 12% in two studies treating patients with hemi or total shoulder arthroplasty. Heuberer, et al. (2018 mixed cohort) reported nine instances (12.3%) of secondary rotator cuff repair post-operatively requiring revision and Hawi, et al. (2017 mixed cohort) reported six instance of rotator cuff deficiency, but only two events required secondary intervention. Follow-up in these studies ranged from nearly 5 years to over 9 years post-op. Both authors concluded the rates align with literature for total shoulder arthroplasty, where secondary cuff failure is the primary reason for revision. Secondary glenoid erosion, specific to the glenoid component, was reported in eight patents in a single study. Johansson, et al. (2018) reported a higher rate of infection in the ECLIPSE group (9.8%); however, the authors noted limitations in the study and potential bias in the patient population. These events are anticipated with shoulder surgery, and were considered by the authors to be comparable to or better than controls or similar studies for stemmed shoulder devices.

Conclusion

The Arthrex Eclipse Shoulder Prosthesis has the same intended use and the same fundamental scientific technology as the Arthrex Univers II Shoulder Prosthesis System, Sidus Stem-Free Shoulder, and Simpliciti Shoulder System. Based on the clinical data, non-clinical data, and literature review presented in this 510(k) for the subject and predicate devices, Arthrex concludes that the proposed device is substantially equivalent to the currently marketed predicate devices.

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)*
K183194

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)

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