September 11, 2019

Catalyst OrthoScience, Inc.
Dale Davison
Sr. VP of Manufacturing & Product Development
14710 Tamiami Trail North, Suite 102
NAPLES FL 34110

Re: K191811
Trade/Device Name: Catalyst OrthoScience CSR Shoulder System
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT
Dated: August 9, 2019
Received: August 12, 2019

Dear Dale Davison:

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)*
K191811

Device Name

Catalyst OrthoScience CSR Shoulder System

Indications for Use *(Describe)*

The Catalyst CSR Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint where hemi- or total shoulder arthroplasty is determined by the surgeon to be the preferred method of treatment. The Catalyst CSR Shoulder System is intended for use in patients with the following conditions where the humeral head, neck and glenoid vault are of sufficient bone stock and the rotator cuff is intact or reconstructable.

- Osteoarthritis
- Avascular Necrosis
- Rheumatoid Arthritis
- Post-traumatic Arthritis
- Correction of functional deformity

The Catalyst CSR humeral and glenoid implants are intended for cemented use.
The Catalyst CSR Press-Fit humeral implants are intended for uncemented or cemented use.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Form FDA 3881

510(k) Summary

Prepared: July 1, 2019

Submitter:
Catalyst OrthoScience, Inc.
14710 Tamiami Trail North, Suite 102
Naples, FL 34110

Contact:
Dale Davison
Sr. VP of Manufacturing & Product Development
Catalyst OrthoScience, Inc.
1-239-325-9976 ext 102
ddavison@catalystortho.com

Proprietary Name: Catalyst OrthoScience CSR Shoulder System

Common Name: Shoulder Prosthesis

Classification Names: 21 CFR 888.3650: Shoulder joint metal/polymer non-constrained cemented prosthesis; Class II

Product Codes: KWT

Substantially Equivalent Devices:

- Catalyst OrthoScience CSR 3 Peg Glenoids, K173812
- Exactech® Equinoxe® UHMWPE 16° Posterior Augment Pegged Glenoids, K121220
- DePuy Anchor Peg Glenoid, K981487

Device Description:

The Catalyst CSR Shoulder System is a bone preserving total shoulder prosthesis designed for use in patients where the humeral head, neck and glenoid vault are of sufficient bone stock and there is an intact or reconstructable rotator cuff. The design requires minimal bone resection, thus giving the patient an alternative to other total shoulder designs where more bone is removed.

This submission adds augmented glenoid components to the CSR Shoulder System. The CSR Augmented Glenoids are nearly identical to the previously cleared CSR 3 Peg Glenoids, except that additional material has been added to the fixation surface creating a 10 degree posterior wedge. Like the previously cleared CSR 3 Peg glenoid components, the CSR Augmented Glenoid components are manufactured from UHMWPE conforming to ASTM F648. Also like the previously cleared CSR 3 Peg Glenoid components, three sizes of augmented glenoid components are available. The bearing surface has a symmetrical, oval shaped profile allowing use of each component on either the right or the left side. The glenoid component is designed to allow insertion at an angle, in the same orientation as the surgeon's exposure, to reduce the forceful retraction and bone and soft tissue trauma usually required to insert standard glenoid components.

Three backside pegs are engineered to provide implant fixation within the dense cortical and subchondral bone.

The CSR Augmented Glenoid components are compatible with previously cleared CSR and CSR Press-Fit humeral components.

Intended Use / Indications:

The Catalyst CSR Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint where hemi- or total shoulder arthroplasty is determined by the surgeon to be the preferred method of treatment. The Catalyst CSR Shoulder System is intended for use in patients with the following conditions where the humeral head, neck and glenoid vault are of sufficient bone stock and the rotator cuff is intact or reconstructable.

- Osteoarthritis
- Avascular Necrosis
- Rheumatoid Arthritis
- Post-traumatic Arthritis
- Correction of functional deformity

The Catalyst CSR humeral and glenoid implants are intended for cemented use.
The Catalyst CSR Press-Fit humeral implants are intended for uncemented or cemented use.

Summary of Technologies/Substantial Equivalence:

The Catalyst CSR Augmented Glenoid components are substantially equivalent to the predicate CSR 3 Peg Glenoid components in regards to intended use and indications, material and design. The addition of posterior augments does not raise different questions of safety and effectiveness.

Non-Clinical Testing:

The CSR Augmented Glenoids were tested for glenoid stability per ASTM F2028-14 with results demonstrating that their performance is adequate for their intended use. Bacterial Endotoxin Testing was performed using the *Limulus* Amebocyte Lysate (LAL) test on worst case components. Results demonstrate that the CSR Augmented Glenoids meet an endotoxin limit of <1.2 EU/device.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Catalyst CSR Augmented Glenoids to the predicate devices.