January 11, 2019

Catalyst OrthoScience, Inc.
Dale Davison
Sr. VP of Manufacturing & Product Development
14710 Tamiami Trail North
Naples, Florida 34110

Re: K182500
Trade/Device Name: Catalyst CSR Press-Fit Humeral Components
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder Joint Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KWT, HSD
Dated: December 5, 2018
Received: December 7, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqi -S

Digitally signed by Vesa Vuniqi -S
Date: 2019.01.11 14:05:05 -05'00'

For: Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K182500

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)*

K182500 **510(k) Summary**

Prepared:	December 4, 2018
Submitter:	Catalyst OrthoScience, Inc. 14710 Tamiami Trail North 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 CSR Shoulder System
Common Name:	Shoulder Prosthesis
Classification Names:	21 CFR 888.3650: Shoulder joint metal/polymer non-constrained cemented prosthesis; Class II 21 CFR 888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis; Class II
Product Codes:	KWT, HSD
Substantially Equivalent Devices	◆ Catalyst OrthoScience CSR Shoulder System, K152825 ◆ Catalyst OrthoScience CSR Shoulder System, K181287 ◆ Exactech Equinoxe Resurfacing System, K131298 ◆ Biomet Copeland Resurfacing Heads, K003044

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 Press-Fit Humeral Components to the CSR Shoulder System. The press-fit humeral components have a non-spherical polished surface for articulation with the glenoid component or the glenoid cavity of the scapula. The humeral components incorporate 4 pegs which assist with alignment and provide rotational stability. The four plane geometry of the back side of the humeral component matches four cut surfaces on the humeral head to recreate the geometry and thickness of the removed bone. The CSR Press-Fit Humeral Components are manufactured from cast Co-Cr-Mo alloy conforming to ASTM F75. The undersurface of the head and the proximal portion of the alignment pegs are coated with a plasma sprayed coating of CP Ti conforming to ASTM F1580.

The CSR humeral components are compatible with previously cleared CSR and CSR 3 Peg glenoid 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 Press-Fit Humeral Components are substantially equivalent to the predicate devices in regards to intended use and indications, materials, design and sizes. The press-fit indication and the addition of a plasma sprayed coating are similar to other predicate devices and do not raise new types of safety and effectiveness questions, nor are there new technological issues.

Non-Clinical Testing:

Static shear testing was conducted and demonstrated that the fixation strength of the Catalyst CSR Press-Fit Humeral Components, tested in shear, met the pre-determined acceptance criterion. An engineering analysis of torque-out of the predicate Catalyst CSR Humeral Components was determined to be applicable to the Catalyst CSR Press-Fit Humeral Components as well. Bacterial Endotoxin Testing was performed. The Catalyst CSR Press-Fit Humeral Components met the acceptable endotoxin limit of <10EU/component or <20EU/device construct.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Catalyst CSR Press-Fit Humeral Components to the predicate devices.