July 12, 2018

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

Re: K181287
Trade/Device Name: Catalyst 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, HSD
Dated: June 11, 2018
Received: June 12, 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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,

Mark N. Melkerson -S

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)*

K181287

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

Both components of the Catalyst CSR Shoulder System are intended for cemented use only.

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: May 15, 2018

Submitter: Catalyst OrthoScience, Inc.
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Naples, FL 34110

Contact: Dale Davison
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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 Device:
- Catalyst OrthoScience CSR Shoulder System (K152825)

Reference Devices:
- Biomet Versa-Dial Humeral Head Prosthesis (K060716)
- Zimmer Anatomical Shoulder Humeral Head and Anatomical Shoulder Keeled Glenoid (K053274, K051623)
- Tornier Aequalis PerFORM+ Shoulder System (K160975)

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 larger, standard (non-spherical) humeral components to the CSR Shoulder System. Like the previously cleared CSR humeral components, the Size H and Size I CSR standard humeral components are manufactured from cast Co-Cr-Mo alloy conforming to ASTM F75. They 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 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

Both components of the Catalyst CSR Shoulder System are intended for cemented use only.

Summary of Technologies/Substantial Equivalence:

The additional Catalyst CSR humeral components are substantially equivalent to the predicate devices in regards to intended use and indications, material and design. The larger sizes do not raise new types of safety and effectiveness questions, nor are there new technological issues.

Non-Clinical Testing:

Static lever-out testing, endotoxin testing, size comparison and radial mismatch comparisons were performed on worst case CSR humeral components. The results indicate that the performance of the Catalyst CSR humeral components is adequate for their intended use.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the new Catalyst CSR humeral components to the predicate devices.