DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 11, 2016

Catalyst Orthoscience LLC
Mr. Stephen Herrington
Chief Executive Officer
5867 Whisperwood Ct
Naples, Florida 34110

Re: K152825
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: April 1, 2016
Received: April 6, 2016

Dear Mr. Herrington:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152825

Device Name
Catalyst 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Prepared: April 1, 2016

Submitter:
Catalyst OrthoScience LLC
5867 Whisperwood Ct
Naples, FL 34110

Contact:
Stephen Herrington
Chief Executive Officer,
Catalyst OrthoScience LLC
1-800-587-5137
sherrington@catalystortho.com

Proprietary Name: Catalyst CSR Shoulder System

Common Name: Resurfacing Total 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:
- Exactech Equinoxe Resurfacing System (K131298)
- Arthrosurface HemiCAP System (K023096, K091196)
- DePuy Global C.A.P and Anchor Peg Glenoid (K031971, K981487)
- Biomet Copeland Resurfacing Heads (K003044)
- Tornier Aequalis PerFORM+ Shoulder System (K150583)

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.

The Catalyst CSR glenoid components are manufactured from UHMWPE conforming to ASTM F648. Three sizes of glenoid components are available, with right and left sides. 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. Two backside anchoring elements are engineered to match the shape of the glenoid vault and provide implant fixation within the dense cortical and subchondral bone. The triangular shape of the anchoring elements combines attributes of both peg and keel designs to resist loosening forces.

The Catalyst CSR humeral components are manufactured from cast Co-Cr-Mo alloy conforming to ASTM F75 and have a polished surface for articulation with the glenoid component or the glenoid cavity of the scapula. The humeral components are designed with standard (non-spherical) and spherical geometries. The standard humeral components have seven sizes and the spherical humeral components have six sizes. 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.

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 Catalyst CSR Shoulder System is substantially equivalent to the predicate devices in regards to intended use and indications, materials, size ranges, and design intent. Any noted differences do not raise new types of safety and effectiveness questions.

Non-Clinical Testing:

Characterization of the UHMWPE, lever-out and torque-out testing of the glenoid components, dynamic shear testing of the glenoid components, lever-out testing and torque-out calculations of the humeral components, and testing of glenoid stability per ASTM F2028-14 were conducted. The results of these tests indicate that the performance of the Catalyst CSR Shoulder System is adequate for its intended use.

Clinical Testing:

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