Catalyst OrthoScience, Inc.
Dale Davison
Senior VP - Product Development
14710 Tamiami Trail North
Naples, Florida 34110

November 10, 2022

Re: K222317
Trade/Device Name: Catalyst EA Convertible Stemmed Shoulder
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD, PHX
Dated: September 23, 2022
Received: September 23, 2022

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,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2022.11.10 15:27:28 -05'00'

For Victoria Lilling, M.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222317

Device Name

Catalyst EA Convertible Stemmed Shoulder

Indications for Use *(Describe)*

The Catalyst EA Convertible Stemmed Shoulder is intended for use as a replacement of shoulder joints in anatomic or reverse arthroplasty. Should the need arise for a conversion from an anatomic total shoulder to a reverse total shoulder, the humeral stem can remain in place, while the articulating surfaces are exchanged.

Anatomic Total Shoulder or Hemi-Shoulder

The Catalyst EA Convertible Stemmed Shoulder 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 EA Convertible Stemmed Shoulder 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 3-Peg glenoid implants are intended for cemented use only.
The Catalyst R1 Reverse Shoulder humeral stems are intended for cemented or uncemented applications.

Reverse Total Shoulder

The Catalyst EA Convertible Stemmed Shoulder is a reverse total shoulder replacement for patients with a functional deltoid muscle and a grossly deficient rotator cuff joint suffering from pain and dysfunction due to:

- Severe arthropathy with a grossly deficient rotator cuff;
- Previously failed joint replacement with a grossly deficient rotator cuff;
- Fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder including humeral head fracture, displaced 3- or 4-part fractures of proximal humerus, or reconstruction after tumor resection;
- Bone defect in proximal humerus;
- Non-inflammatory degenerative disease including osteoarthritis and avascular necrosis of the natural humeral head and/or glenoid;
- Inflammatory arthritis including rheumatoid arthritis;
- Correction of functional deformity

The Catalyst R1 Shoulder humeral stems are intended for uncemented or cemented applications.
The glenoid baseplate is intended for uncemented use with the addition of screws for fixation.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Prepared Date:	November 10, 2022
Submitter:	Catalyst OrthoScience, Inc. 14710 Tamiami Trail North, Suite 102 Naples, FL 34110
Contact:	Dale Davison Sr. VP of Manufacturing & Product Development 1-239-325-9976 ext. 102 ddavison@catalystortho.com
Proprietary Name:	Catalyst EA Convertible Stemmed Shoulder
Common Name:	Shoulder Prosthesis
Classification Name:	21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis; Class II 21 CFR 888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis; Class II
Product Code:	KWS, HSD, PHX
Primary Predicate:	Encore Medical (DJO) AltiVate Shoulder System K172351
Secondary Predicate:	Catalyst CSR Shoulder System, K182500

Device Description:

The Catalyst EA Convertible Stemmed Shoulder is an anatomic designed total shoulder prosthesis that mates with the Catalyst R1 humeral stems cleared in K202611.

This submission adds conversion adapters, locking screw and humeral heads to mate with the previously cleared Catalyst R1 humeral stems. The humeral head components are compatible with previously cleared CSR 3 Peg glenoid components or for articulation with the glenoid cavity of the scapula. When the humeral stem (cleared K202611), adapter and humeral head are mated together, this creates a hemiarthroplasty (product code HSD). When the humeral stem, adapter and humeral head are used in conjunction with the CSR glenoid components (cleared K191811 and K173812), this creates a total shoulder arthroplasty (product code KWS). The adapters and locking screw are manufactured from Ti-6Al-4V ELI conforming to ASTM F136. The humeral components are manufactured from Co-Cr-Mo alloy conforming to ASTM F1537.

The Anatomic system consists of a humeral stem, adapter, locking screw and articulating head. The adapters are secured to the stem using a locking screw. The articulating humeral heads are secured to the adapter by a taper lock. The articulating head components have a polished surface for articulation with the compatible Catalyst 3-Peg Glenoid component or the glenoid cavity of the scapula.

The Reverse system consists of a humeral stem, articulating insert, central baseplate, glenosphere, fixation elements and locking components. The central baseplate is a circular disc that rests against the glenoid bone and is secured to the bone using up to four 4.5mm peripheral screws and either a central 6.5mm screw or post. The glenosphere is secured to the central baseplate by a taper lock, with the additional fixation of a locking or compression screw.

Intended Use / Indications:

The Catalyst EA Convertible Stemmed Shoulder is intended for use as a replacement of shoulder joints in anatomic or reverse arthroplasty. Should the need arise for a conversion from an anatomic total shoulder to a reverse total shoulder, the humeral stem can remain in place, while the articulating surfaces are exchanged.

Anatomic Total Shoulder or Hemi-Shoulder

The Catalyst EA Convertible Stemmed Shoulder 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 EA 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 3-Peg glenoid implants are intended for cemented use only.
The Catalyst R1 Shoulder humeral stems are intended for uncemented or cemented applications.

Reverse Total Shoulder

The Catalyst EA Convertible Stemmed Shoulder is a reverse total shoulder replacement for patients with a functional deltoid muscle and a grossly deficient rotator cuff joint suffering from pain and dysfunction due to:

- Severe arthropathy with a grossly deficient rotator cuff;
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- Fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder including humeral head fracture, displaced 3- or 4-part fractures of proximal humerus, or reconstruction after tumor resection;
- Bone defect in proximal humerus;
- Non-inflammatory degenerative disease including osteoarthritis and avascular necrosis of the natural humeral head and/or glenoid;
- Inflammatory arthritis including rheumatoid arthritis;
- Correction of functional deformity

The Catalyst R1 Shoulder humeral stems are intended for uncemented or cemented applications. The glenoid baseplate is intended for uncemented use with the addition of screws for fixation.

Comparison of Technologies/Substantial Equivalence:

The Catalyst EA Convertible Stemmed Shoulder is substantially equivalent to the predicate devices in regard to intended use and indications, materials, size ranges, and design intent. Any noted differences do not raise new types of safety and effectiveness questions, nor are there new technological issues.

Non-Clinical Testing:

Range of motions analyses, biocompatibility assessment and construct fatigue testing were all conducted. Axial disassembly tests were performed pre-fatigue and post-fatigue testing. The construct fatigue testing demonstrated that the construct strength of the Catalyst EA Convertible Stemmed Shoulder humeral heads with conversion adapter, met the pre-determined acceptance criterion. All testing has determined that the device is substantially equivalent to the predicate device.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Catalyst EA Convertible Stemmed Shoulder to the predicate devices.

Conclusions:

The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is substantially equivalent to the legally marketed device predicate. The intended use, indications, materials, size ranges and design intent are all equivalent and any noted differences do not raise different questions of safety and effectiveness.