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

February 12, 2021

Re: K202611
Trade/Device Name: Catalyst OrthoScience R1 Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, HSD
Dated: January 12, 2021
Received: January 13, 2021

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,

Michael Owens
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)*
K202611

Device Name

Catalyst R1 Reverse Shoulder System

Indications for Use *(Describe)*

The Catalyst R1 Reverse Shoulder System 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 humeral stems are intended for cemented or uncemented 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.

510(k) Summary

Prepared: February 12, 2021

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 R1 Reverse Shoulder System

Common Name: Shoulder Prosthesis

Classification Name: 21 CFR 888.3660 - Shoulder joint metal/polymer semi-constrained cemented prosthesis

21 CFR 888.3690 – Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis

Regulatory Class: Class II

Product Code: PHX – Shoulder Prosthesis, Reverse Configuration

HSD – Shoulder Prosthesis, Hemi-, Humeral, Metallic, Uncemented

Substantially Equivalent Devices:

Primary Predicate:

- Encore Medical (DJO) Altivate Reverse Shoulder System (K141990, K172351 and K190290)

Secondary Predicates:

- FX Solutions Humelock Reversed Shoulder (K162455)
- Arthrex Univers Revers Modular Glenoid (K173900, K193372)

Device Description:

The Catalyst R1 Reverse Shoulder System is a total shoulder prosthesis designed for use in patients with a non-functional rotator cuff. The articulation of this reverse design is inverted compared to a traditional anatomic total shoulder prosthesis, where the articulating sphere is on the glenoid side of the joint, and the mating insert is fixed into the humeral stem implant.

The humeral implant system consists of humeral stems and polyethylene inserts. The stem implants are manufactured from Ti-6Al-4V ELI conforming to ASTM F136 with a porous structure on the proximal portion. The humeral stems are offered in short and long stem configurations to accommodate varying bone geometries. The humeral articulating inserts are manufactured from UHMWPE conforming to ASTM F648. They have a concave bearing geometry that radially matches the different sized glenospheres and are offered in varying thicknesses to achieve stability of the glenohumeral joint.

The glenoid implant system consists of a central baseplate, glenosphere, fixation components, 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 peripheral screws and either a central screw or post. The baseplate is manufactured from Ti-6Al-4V ELI conforming to ASTM F136 with a titanium plasma spray on the bone facing surface. The baseplate is offered in standard and augmented configurations. The Co-Cr-Mo glenospheres are manufactured from CoCrMo conforming to ASTM F1537 and are secured to the baseplate by a taper lock, and with an additional locking screw. The fixation components are manufactured from Ti-6Al-4V ELI conforming to ASTM F136.

Intended Use / Indications For Use:

The Catalyst R1 Reverse Shoulder System 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 humeral stems are intended for cemented or uncemented applications.

The glenoid baseplate is intended for uncemented use with the addition of screws for fixation.

Comparison of Technologies/Substantial Equivalence:

The Catalyst R1 Reverse 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, nor are there new technological issues.

Performance Data / Non-Clinical Testing:

Range of motion analyses, complete construct fatigue testing per ASTM F1378, post-fatigue disassembly testing, and testing of glenoid stability per ASTM F2028 were completed. The results of these tests indicate that the performance of the Catalyst R1 Reverse Shoulder is adequate for its intended use. Chemical characterization per ISO 10993 Part 18, Cytotoxicity and Pyrogenicity testing were also conducted on the implant materials. The Catalyst R1 Reverse Shoulder met the recommended pyrogenicity limit of <20 EU/device.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Catalyst R1 Reverse Shoulder System to the predicate devices.

Conclusions

The Catalyst R1 Reverse Shoulder System is substantially equivalent to the predicate devices. The subject device has the same design features, uses the same materials, has the same intended use and indications, has the same size ranges, and the same design intent as the predicate devices. Any noted differences do not raise new types of safety and effectiveness questions, nor are there new technological issues. The testing performed and results indicate that the Catalyst R1 Reverse Shoulder System is equivalent to the predicate devices.