September 20, 2023

Catalyst OrthoScience, Inc.
Dale Davison
Sr VP - Manufacturing and Product Development
14710 Tamiami Trail N.
Naples, Florida 34110

Re: K232583
Trade/Device Name: Catalyst 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
Dated: August 23, 2023
Received: August 25, 2023

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: 2023.09.20 17:02:08 -04'00'

Farzana Sharmin, Ph.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)*

K232583

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.

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510(k) Summary

Prepared:	September 19, 2023
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
Regulatory Class:	Class II
Product Code:	PHX – Shoulder Prosthesis, Reverse Configuration
Primary Predicate:	Catalyst R1 Reverse Shoulder System K211991
Additional Predicate:	TORNIER (Stryker) Aequalis Ascend Flex Shoulder System K151293

Device Description:

The Catalyst OrthoScience 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.

This submission is to add polyethylene inserts with a modified locking ring to the R1 Reverse Shoulder System. These polyethylene inserts are a design modification of the polyethylene inserts cleared in K202611 and K211991. There are no changes to the articulating interface or overall dimensions of the construct in vivo, the only change is to the locking mechanism. These polyethylene inserts do not replace the standard polyethylene inserts cleared in K202611 and K211991 but are an additional option and are compatible with all components within the Catalyst R1 Reverse Shoulder System.

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:

The polyethylene inserts with modified locking rings are substantially equivalent to the predicate device regarding intended use and indications, size ranges, and design intent. Any noted differences do not raise different questions of safety and effectiveness.

Performance Data / Non-Clinical Testing:

Construct fatigue tests were completed, and post fatigue tests included axial and torsional disassembly tests. The results of these tests indicate that the performance of the Catalyst R1 Reverse Shoulder is adequate for its intended use.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Catalyst R1 Reverse Shoulder System polyethylene inserts with modified locking ring to the predicate device.

Conclusions

The Catalyst R1 Reverse Shoulder System polyethylene inserts with modified locking rings are substantially equivalent to the predicate device. 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 different questions of safety and effectiveness. The tests performed and results indicate the subject device is substantially equivalent to the predicate device.