November 6, 2025

Catalyst OrthoScience, Inc.
Dale Davison
Sr VP - Product Develpment
14710 Tamiami Trail, North suite 102
Naples, Florida 34110

Re: K252418
Trade/Device Name: Catalyst F1x Shoulder System
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: October 1, 2025
Received: October 2, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2025.11.06 11:18:25 -05'00'

Farzana Sharmin, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252418

Please provide the device trade name(s).

Catalyst F1x Shoulder System

Please provide your Indications for Use below.

The Catalyst F1x Shoulder System 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 F1x 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 F1x 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

REVERSE TOTAL SHOULDER

The Catalyst F1x 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;
- 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

Catalyst F1x press-fit stems are intended for cementless press-fit applications.

The Catalyst F1x cemented stems are intended for cemented fixation.

The Catalyst F1x stem is compatible with the implants from the Catalyst CSR System, Catalyst EA Convertible Shoulder System and R1 Shoulder Systems.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Prepared Date:	November 4, 2025
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 F1x Shoulder System
Common Name:	Shoulder Prosthesis
Classification Name:	21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis; Class II
Product Code:	KWS, PHX, HSD
Primary Predicate:	Catalyst EA Convertible Stemmed Shoulder System (K222317)
Reference Device:	Catalyst F1x Shoulder System (K234105)

Device Description:

The Catalyst F1x Shoulder System is intended for use as a replacement of shoulder joints in anatomic or reverse arthroplasty. The stems can be used in conjunction with the Catalyst R1 Reverse Shoulder humeral articulating poly inserts and glenoid implants for use in reverse shoulder arthroplasty. The stems can also be used in conjunction with the Catalyst Convertible System and CSR System for use in total or hemi-shoulder arthroplasty. The design intent of the Catalyst F1x Shoulder System is to offer a unique solution for revision shoulder arthroplasty and for securing and immobilizing the greater and lesser tuberosities in the repair of proximal humerus fractures.

This submission for the Catalyst F1x Shoulder System is to add anatomic indications for the Catalyst F1x Shoulder System. This submission consists of proximal bodies, distal stems and locking screws. The fracture specific proximal bodies have asymmetric, right- and left-sided finned geometry to provide specific locations to reattach the greater and lesser tuberosities for a stable reconstruction of the proximal humerus. The proximal bodies will have a porous titanium structure on the bone engaging regions to enhance the mechanical fixation. The distal stems shall be provided in varying diameters to accommodate varying bone geometries. The distal stems will be offered in press-fit and cemented versions. The press-fit distal stems shall have a tapered, splined proximal geometry with an HA (hydroxyapatite) coating. The cemented stems shall have

a smooth stem geometry. The proximal bodies and distal stems shall be secured together using a mechanical taper interface that is supplemented with a locking screw.

Intended Use / Indications:
The Catalyst F1x Shoulder System 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 F1x 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 F1x 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
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- Rheumatoid Arthritis
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- Correction of functional deformity

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The Catalyst F1x 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;
- 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

Catalyst F1x press-fit stems are intended for cementless press-fit applications.
The Catalyst F1x cemented stems are intended for cemented fixation.
The Catalyst F1x stem is compatible with the implants from the Catalyst CSR System, Catalyst EA Convertible Stemmed Shoulder System and R1 Shoulder Systems.

Comparison of Technological Characteristics:

The Catalyst F1x Shoulder System was cleared on 4/5/2024 and is in clinical use. This submission adds anatomic indications for the Catalyst F1x Shoulder System and is similar to the predicate device in regard to materials, size ranges, and design intent.

Non-Clinical Testing:

The following non-clinical testing was conducted to support substantial equivalence:

- Range of Motion assessment
- Construct fatigue testing
- Disassembly Testing
- Fretting Corrosion Assessment

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Catalyst F1x Shoulder System to the predicate devices.

Conclusions:

The conclusions drawn from the nonclinical tests demonstrate that the device is substantially equivalent to the legally marketed predicate identified in this 510(k) Summary.