September 26, 2025

Shoulder Innovations, Inc.
Mark Hanes
Senior Technical Director
1535 Steele Ave SW, Suite B
Grand Rapids, Michigan 49507

Re: K252221
Trade/Device Name: Inset Reverse Total 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, MBF
Dated: July 15, 2025
Received: July 16, 2025

Dear Mark Hanes:

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: 2025.09.26 09:13:41 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252221

Device Name
InSet Reverse Total Shoulder System

Indications for Use *(Describe)*
Reverse Total Shoulder:

The Inset Reverse Total Shoulder System should be used in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The Inset Reverse Total Shoulder System is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. The System can be used to treat fractures of the humeral head, and revision of other devices if sufficient bone stock remains.

The Glenoid Baseplate is intended for cementless application with the addition of screw fixation. The Humeral Stem may be implanted by press-fit or cement 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

Date Prepared:	September 24, 2025
Submitter:	Shoulder Innovations, Inc. 1535 Steele Ave SW, Suite B Grand Rapids, MI 49507
Contact:	Mark D. Hanes, Ph.D Sr. Technical Director Shoulder Innovations, Inc. (574) 575-0903 Mark.Hanes@GenesisInnovationGroup.com
Proprietary Name:	InSet Reverse Total Shoulder System
Common Name:	Shoulder Prosthesis, Reverse Configuration
Classification Name:	Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulation Number:	21 CFR 888.3660
Classification Code:	PHX, MBX
Review Panel:	Orthopedic
Predicate Devices:	Primary Predicate K122698 – Aequalis Ascend FlexFlex Shoulder System Secondary Predicate K210533 – Inset Reverse Total Shoulder System

SHOULDER INNOVATIONS

Device Description:

This submission represents a product line extension to add the InSet 95 Humeral Stem to the InSet Reverse Total Shoulder System, previously cleared under K210533. No additional modifications are proposed to the cleared InSet Reverse Total Shoulder System components as part of this submission.

The InSet Reverse Total Shoulder System is intended for total shoulder replacement in a reverse shoulder configuration. Unlike traditional (anatomic) total shoulder arthroplasty, a reverse shoulder configuration places the ball component (glenosphere) on the glenoid side and the polyethylene bearing surface on the humeral side. The cleared system (K210533) comprises humeral components—Humeral Stem, Humeral Tray, and Humeral Bearing—and glenoid components—Glenosphere Baseplate, Peripheral Screws, Central Compression Screw (optional), Baseplate Set Screw Locking Nut, Glenosphere, and Glenosphere Locking Bolt. Again, no changes to these cleared components are proposed in this submission.

In the system, the Glenosphere Baseplate is affixed to the native glenoid bone using a Central Compression Screw and Peripheral Screws. The baseplate features a female taper for assembly with the selected Glenosphere. Glenoid components are intended for press-fit, cementless fixation, supplemented by screw fixation. On the humeral side, the selected Humeral Bearing attaches to the Humeral Tray, which is assembled with the Humeral Stem (cleared under K173824). Humeral stems may be used either uncemented (press-fit) or with bone cement.

The materials used in the system include:

- **Titanium Alloy (ASTM F136)**: Used for the humeral stem, glenoid baseplate, modular tray, compression screw, and supplemental screws
- **Commercially Pure Titanium (ASTM F67)**: Used for the porous coating on the proximal portions of the humeral stem and glenoid baseplate
- **Cobalt-Chromium Alloy (ASTM F1537)**: Used for the Glenosphere
- **Ultrahigh Molecular Weight Polyethylene (UHMWPE, ASTM F648)**: Used for the Humeral Bearing

The InSet 95 Humeral Stem is an identical implant component used in both the subject device (InSet Reverse Total Shoulder System with InSet 95 Humeral Stem) and the primary predicate device (Aequalis Ascend FlexFlex Shoulder System, cleared under K122698).

In the subject configuration, the InSet 95 Humeral Stem consists of modular, collarless stems and humeral trays and humeral bearings designed to articulate with a glenosphere component. The stems are made from Titanium Alloy (Ti-6Al-4V) and feature longitudinal fins to enhance rotational stability. The collarless design coupled with the humeral tray helps mitigate the risk of stem subsidence. Each stem has a female Morse-type taper for modular tray attachment. The proximal portion, including the fins, is covered with a rough, porous coating to facilitate

uncemented fixation, though cemented use is also permitted.

Indications for Use:

Reverse Total Shoulder:

The Inset Reverse Total Shoulder System should be used in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The Inset Reverse Total Shoulder System is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. The System can be used to treat fractures of the humeral head, and revision of other devices if sufficient bone stock remains.

The Glenoid Baseplate is intended for cementless application with the addition of screw fixation.

The Humeral Stem may be implanted by press-fit or cement fixation.

Proposed Modification:

The subject of this submission is a product line extension to incorporate the InSet 95 Humeral Stem into the Shoulder Innovations InSet Reverse Total Shoulder System (cleared under K210533). These fracture treatment indications are applicable only when the InSet Reverse Total Shoulder System is used in conjunction with the InSet 95 Humeral Stem.

The proposed InSet 95 Humeral Stem is a collarless design, wherein the modular humeral tray functions as a collar to help prevent stem subsidence. The stem is manufactured from titanium alloy conforming to ASTM F136 and includes longitudinal fins for enhanced rotational stability. These fins are coated with a rough, porous surface of commercially pure titanium in accordance with ASTM F1580 to facilitate uncemented fixation.

The InSet 95 Humeral Stem features a fixed neck angle of 132.5 degrees and incorporates a female Morse-type taper for compatibility with the modular humeral trays of the cleared InSet Reverse Total Shoulder System. The stem is indicated for both press-fit (uncemented) and cemented use.

Comparison of Technological Characteristics:

The Shoulder Innovations InSet Reverse Total Shoulder System with the InSet 95 Humeral Stem is substantially equivalent to the primary predicate device in terms of intended use and technological characteristics. Both the subject device and the primary predicate device are intended for use as orthopedic implant systems for shoulder arthroplasty, designed to restore joint function and alleviate pain in patients requiring total shoulder joint replacement.

The InSet 95 Humeral Stem when used with the InSet Reverse Total Shoulder System will carry the identical fracture-related indications for use (i.e.-treatment of humeral head fractures) as Aequalis Ascend FlexFlex Shoulder System (cleared under K122698). These fracture treatment indications are applicable solely when the InSet Reverse Total Shoulder System is used in conjunction with the InSet 95 Humeral Stem.

Both the subject and primary predicate devices are prosthetic systems intended to partially or totally replace the shoulder joint. Technological characteristics shared between the two devices include identical taper connection design, stem body and contour, fixation and bone integration mechanisms, proximal porous coating, base materials, sterilization methods, and overall compatibility with the InSet Total Shoulder System implant offerings. Any differences in technological characteristics do not raise new questions of safety or effectiveness.

The secondary predicate device differs in its Indications for Use statement, specifically in the absence of fracture-related indications. However, the fracture-related indications included in the subject device are identical to those previously cleared in the primary predicate (K122698). Both the subject and secondary predicate devices are intended for use in the reverse configuration.

Non-Clinical Testing Summary:

The InSet 95 Humeral Stem was evaluated to demonstrate substantial equivalence to the predicate devices. Non-clinical testing included Taper axial dislocation per ASTM F2009, Mechanical Strength evaluation via cyclic fatigue testing, and range of motion analysis.

Clinical Testing Summary:

Clinical testing was not necessary to demonstrate substantial equivalence of the InSet Reverse Total Shoulder System InSet 95 Humeral Stem to the predicate device.

Overall Conclusion:

The InSet Reverse Total Shoulder System with InSet 95 Humeral Stem is substantially equivalent to the Aequalis Ascend FlexFlex Shoulder System (cleared under K122698).