February 11, 2025

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

Re: K241817
Trade/Device Name: InSet Total Shoulder System
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT, KWS, HSD
Dated: January 9, 2025
Received: January 10, 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: 2025.02.11 14:36:19 -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

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.

Submission Number *(if known)*

K241817

Device Name

Inset Total Shoulder System

Indications for Use *(Describe)*

The Shoulder Innovation's InSet Total Shoulder System, when used with the Inset Stem, is intended for use as an orthopedic implant for partial or total shoulder arthroplasty to treat the following:

1. Significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint;
2. Fractures of the humeral head
3. Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
4. Avascular necrosis of the humeral head
5. Revision where other devices or treatments have failed.

The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty.

The InSet Total Shoulder System components are intended for single use only. The glenoid component is intended for cemented fixation only; 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.

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

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510(k) Summary

Date Prepared:	February 7, 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 Total Shoulder System
Common Name:	Shoulder Prosthesis
Classification Name:	Shoulder Joint Metal/Polymer Non-Constrained Cemented Prosthesis
Regulation Number:	21 CFR 888.3650
Classification Code:	KWT KWS HSD
Review Panel:	Orthopedic
Substantially Equivalent Devices:	Primary Predicate K192365 – Shoulder Innovations, Total Shoulder System Additional Predicate K212737 – INHANCE™ Reverse Shoulder System Additional Predicate K060692 – Comprehensive® Primary Shoulder Stems

Device Description:

The Shoulder Innovations Total Shoulder System consists of modular humeral stems and heads that articulate with a glenoid component. The humeral stems are collarless and manufactured from Titanium Alloy (Ti6-4) with fins to provide rotational stability. The collarless stems allow the humeral head to prevent stem subsidence. The stems have a female Morse-type taper to interface with the modular humeral heads. The proximal body and fins are coated with a rough, porous coating for un-cemented fixation or for use with bone cement.

The humeral heads are manufactured from CoCr and are available in standard and offset configurations. The heads have a male Morse-type taper to interface with the humeral stems.

The glenoid components of the Total Shoulder System are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE). The glenoid implant is a pegged design intended for cemented fixation only.

Indications for Use:

The Shoulder Innovation's InSet Total Shoulder System, when used with the InSet Stem, is intended for use as an orthopedic implant for partial or total shoulder arthroplasty to treat the following:

1. Significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint;
2. Fractures of the humeral head
3. Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
4. Avascular necrosis of the humeral head
5. Revision where other devices or treatments have failed.

The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty.

The InSet Total Shoulder System components are intended for single use only. The glenoid component is intended for cemented fixation only; 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 add the InSet 95 Humeral Stem to the Shoulder Innovations InSet Total Shoulder System (K192365 and K173824). The InSet 95 Humeral Stem carries the same indications for use as the InSet Total Shoulder System with an additional indication for the treatment of humeral fractures. The fracture treatment indication is limited solely to the InSet Total Shoulder System when used with the InSet 95 Humeral Stem.

As with the predicate InSet Total Shoulder System humeral stems, the proposed InSet 95 Humeral Stem is collarless, the humeral head acts as the collar to prevent stem subsidence. The InSet 95 Humeral Stem is manufactured from Titanium Alloy conforming to ASTM F136, with fins to provide rotational stability that are coated with a rough, porous coating of commercially pure titanium according to ASTM F1580. The InSet 95 Humeral Stem has a female Morse-type taper to interface with the cleared InSet Total Shoulder System modular humeral heads. The InSet 95 Humeral Stem is indicated for either press-fit or cemented fixation.

Comparison of Technological Characteristics:

Shoulder Innovations InSet Total Shoulder System with Inset 95 Humeral Stem is substantially equivalent to the primary predicate device in that both the proposed and primary predicate device have the same intended use and have similar technological characteristics. Both the proposed and primary predicate are prosthesis systems intended to be implanted to partially or totally replace a shoulder joint. The technological features characteristics most similar between the proposed device and primary predicate device include identical taper connection design; stem body and contour design; initial fixation, ; proximal porous coating material designed to achieve biological fixation; base materials; sterilization; and device compatibility with full implant offerings in the InSet Total Shoulder System. The differences in technological characteristics do not raise new questions of safety and effectiveness.

Shoulder Innovations InSet Total Shoulder System has similar technological characteristics to the INHANCE™ Reverse Shoulder System, K212737. The proposed subject device and the proposed secondary predicate device has same Indications for Use Statement as follows:

- Revision where other devices or treatments have failed.
- Fractures of the humeral head
- Fractures of the proximal humerus, where other methods of treatment are deemed inadequate

The proposed subject device has the similar technological characteristics as the secondary predicate device, specifically, taper connection design, humeral head design material, fixation method and stem geometry. The difference in technological characteristics do not raise different questions of safety and effectiveness.

Non-Clinical Testing Summary:

The InSet 95 Humeral Stem was evaluated to demonstrate substantial equivalence to the predicate devices. Non-clinical testing included stem mechanical strength evaluation via cyclic fatigue testing.

Clinical Testing Summary:

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

Overall Conclusion:

The InSet Total Shoulder System with InSet 95 Humeral Stem is substantially equivalent to the InSet Total Shoulder System humeral stem components regarding intended use, material, and design. The geometric modifications to create the InSet 95 Humeral Stem indicated for humeral fracture treatment does not raise different questions regarding safety and effectiveness of the device. Non-clinical evaluation demonstrated that subject device is substantially equivalent to the legally marketed predicate device.