April 13, 2026

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

Re: K254128
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: March 5, 2026
Received: March 6, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

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.	K254128

Please provide the device trade name(s).

InSet Reverse Total Shoulder System

Please provide your Indications for Use below.

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 the fractures of the humeral head, fractures of the proximal humerus where other methods of treatment are deemed inadequate (with Standard Humeral Stems), 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.

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

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Date Prepared:	December 20, 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, MBF
Review Panel:	Orthopedic
Predicate Devices:	Primary Predicate K252221 – InSet Reverse Total Shoulder System Secondary Predicate K212737 – INHANCE Shoulder System

Device Description:

This submission represents a product line extension to add the InSet 135 Humeral Stem to the InSet Reverse Total Shoulder System, previously cleared under K252221. No modifications are proposed to the cleared InSet Reverse Total Shoulder System components as part of this submission. The purpose of this 510(k) submission is to obtain FDA clearance for a product line extension adding the InSet 135 Humeral Stem ("I135" or "subject device") and its associated stem-specific instruments to the InSet Reverse Total Shoulder System, and to expand the Indications for Use to include treatment of fractures of the proximal humerus. This fracture indication applies only when the InSet Reverse Total Shoulder System is used in combination with the InSet 135 Humeral Stem.

InSet 135 Humeral Stems are collarless and manufactured from Titanium Alloy (Ti-6Al-4V Extra Low Interstitial, (ELI) per ASTM F136) with a proximal porous coating of Commercially Pure Titanium (CPTi) per ASTM F67, with fins to provide rotational stability; identical to the InSet 95 Humeral Stem (primary predicate device).

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 the fractures of the humeral head, fractures of the proximal humerus where other methods of treatment are deemed inadequate (with Standard Humeral Stems), 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.

Comparison of Technological Characteristics:

The InSet Reverse Total Shoulder System with InSet 135 Humeral Stem is substantially equivalent to the InSet Reverse Total Shoulder System with InSet 95 Humeral Stem (K252221) with respect to intended use, fundamental scientific technology, overall system design, materials, modularity, fixation methods, and sterilization. The InSet 135 Humeral Stem represents a length variant of the previously cleared humeral stem platform and maintains identical design features, material composition, surface characteristics, and taper interface. The proposed expansion of the indications for use to include treatment of fractures of the proximal humerus is supported by the legally marketed INHANCE™ Reverse Shoulder System (K212737), which is cleared under the same regulation and product code. Differences related to stem length, packaging configuration, shelf life, and manufacturing and sterilization sites were evaluated through appropriate non-clinical testing, including mechanical performance testing, cadaver laboratory evaluation, sterilization validation, packaging validation, and shelf-life testing, and were shown not to raise different questions of safety or effectiveness

Non-Clinical Testing Summary:

Non-clinical testing was conducted to demonstrate that the InSet Reverse Total Shoulder System with InSet 135 Humeral Stem performs as intended and is substantially equivalent to the predicate devices. Testing included mechanical evaluation (worst-case fatigue analysis) and taper interface justification. Additional testing, including sterilization validation, packaging validation, shelf-life testing, and pyrogen testing, demonstrated that the subject device meets applicable performance requirements and does not raise different questions of safety or effectiveness.

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 135 Humeral Stem is substantially equivalent to the legally marketed InSet Reverse Total Shoulder System with InSet 95 Humeral Stem (K252221) with respect to intended use, fundamental scientific technology, design, materials, fixation methods, and sterilization. The proposed expansion of the indications for use to include treatment of fractures of the proximal humerus is supported by the legally marketed INHANCE™ Reverse Shoulder System (K212737), which is cleared under the same regulation and product code. Differences between the subject and predicate devices were evaluated through appropriate non-clinical testing and do not raise different questions of safety or effectiveness; therefore, the subject device is substantially equivalent to the identified predicate device.