January 15, 2026

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

Re: K252516
Trade/Device Name: N22 EZ Glenosphere
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: December 13, 2025
Received: December 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

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. | K252516 |

Please provide the device trade name(s).

N22 EZ Glenosphere

Please provide your Indications for Use below.

The InSet Reverse Total Shoulder System should be used in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthoplasty 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 or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

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.

N22 EZ Glenosphere made of Titanium is indicated for patients with a suspected sensitivity to the constituents of CoCr alloy that complies with ASTM F75. The wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy. A Cobalt Alloy Glenosphere is the recommended component for reverse shoulder arthoplasty patients without material sensitivity to the constituents of CoCr alloy.

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

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

# 510(k) Summary

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|---|---|
| **Date Prepared**: | January 14, 2026 |
| **Submitter**: | Shoulder Innovations, Inc.<br>1535 Steele Ave SW, Suite B<br>Grand Rapids, MI 49507 |
| **Contact**: | Mark D. Hanes, Ph.D.<br>Sr. Technical Director<br>Shoulder Innovations, Inc.<br>(574) 575-0903<br>Mark.Hanes@GenesisInnovationGroup.com |
| **Proprietary Name:** | N22 EZ Glenosphere |
| **Common Name:** | Shoulder Prosthesis, Reverse Configuration |
| **Classification Name:** | Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis |
| **Regulation Number:** | 21 CFR 888.3660<br>21 CFR 888.3670 |
| **Classification Code:** | PHX, MBF |
| **Review Panel:** | Orthopedic |
| **Predicate Devices:** | Primary Predicate: Inset Reverse Total Shoulder System (K210533)<br>Reference Device: Identity Shoulder System (K213856) |

## Device Description:

The proposed N22 EZ Glenosphere is manufactured from titanium alloy (Ti-6Al-4V) per F136 featuring a nitrogen ion implantation surface hardening treatment. It is designed for use with the InSet™ Reverse Total Shoulder System components cleared under K210533, maintaining the same dimensional specifications as the cleared CoCr Glenospheres (K210533), with modifications including increased articular surface roughness and a radiused distal end on the male Morse taper. The glenosphere-baseplate construct and humeral assembly mirror those of the predicate device, utilizing a central compression screw with peripheral screws for baseplate fixation and compatible humeral stems (K173824), which allow for press-fit or cemented use. All associated components (humeral stem, tray, baseplate, screws) are made from Ti-6Al-4V per ASTM F136, with porous titanium coating (ASTM F67) on the humeral stem and baseplate.

## Indications for Use:

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 or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

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.

N22 EZ Glenosphere made of Titanium is indicated for patients with a suspected sensitivity to the constituents of CoCr alloy that complies with ASTM F75. The wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy A Cobalt Alloy glenosphere is the recommended component for reverse shoulder arthroplasty patients without material sensitivity to the constituents of CoCr alloy.

## Summary of Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** Identical to primary predicate and reference device
- **Indication for Use:** In comparison to primary predicate device, the subject device is narrowed to patients with known or suspected hypersensitivity to CoCr constituents, while the CoCr glenosphere is intended for general reverse shoulder arthroplasty patients. However, subject device indication for use statement is similar to the reference device
- **Materials:** Identical to reference device
- **Technological Characteristics**: The N22 EZ Glenosphere uses the same fundamental technology as the predicate and reference devices, functioning as a glenosphere in a reverse shoulder arthroplasty system with the same operating principle, anatomical application, and fixation method. The primary technological difference is the use of a titanium alloy substrate (Ti-6Al-4V, ASTM F136) instead of cobalt-chromium alloy; the titanium surface includes a hardening treatment that has been previously cleared by FDA.
- **Sterilization:** Identical to primary predicate device
- **Compatibility**: Identical to primary predicate device

## Non-Clinical Testing Summary:

The subject device- N22 EZ Glenosphere was verified to be substantially equivalent using bench testing methodologies and acceptance criteria previously applied to the predicate device, CoCr Glenosphere cleared under InSet Reverse Total Shoulder System (K210533).

The following non-clinical testing and engineering justifications were performed to support the inclusion of the N22 EZ Glenospheres into the cleared InSet™ Reverse Total Shoulder System (K210533). All testing and analyses were conducted in accordance with FDA guidance and relevant standards.

- Taper Disassembly Testing (includes axial strength and rotational torque)
- Cleaning Validation
- Axial Displacement and Cyclic Fatigue Analysis
- Fretting/Corrosion
- Range of Motion
- Cadaver Design Validation
- Pin on Disk (POD) Testing
- Process Qualification

## Clinical Testing Summary:

Clinical testing was not necessary to demonstrate substantial equivalence of the N22 Glenosphere to the predicate device.

## Overall Conclusion:

The proposed subject device, N22 EZ Glenosphere has the same intended use and indications for use as the predicate device. The proposed device has similar technological characteristics to the predicate, and the information provided herein demonstrates that:

- any differences do not raise different questions of safety and effectiveness; and
- the proposed device is as safe and effective as the legally marketed predicate device.