Shoulder Innovations, Inc.
Don Running
VP R&D
13827 Port Sheldon Street
Holland, Michigan 49424

August 20, 2021

Re: K210533
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 23, 2021
Received: July 27, 2021

Dear Don Running:

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 (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 located 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.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Michael Owens
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210533

Device Name
Inset Reverse Total Shoulder System

Indications for Use *(Describe)*
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.

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: February 15, 2021

Submitter:
Shoulder Innovations, Inc.
13827 Port Sheldon St.
Holland, MI 49424

Contact:
Don Running
Vice President – R&D
Shoulder Innovations
(574) 253-1133
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Proprietary Name: Inset Reverse Total Shoulder System

Common Name: Shoulder Prosthesis

Classifications:
21 CFR Section 888.3660 – Shoulder joint metal/polymer semi-constrained cemented prosthesis; Class II
Product Code: PHX

21 CFR Section 888.3670 - Shoulder joint metal/polymer/ metal nonconstrained or semi-constrained porous-coated uncemented prosthesis; Class II
Product Code MBF

Review Panel: Orthopedic

Primary Predicate Device: Biomet Comprehensive Reverse Shoulder (K080642)

Secondary Predicate Devices:
Biomet Comprehensive Reverse Shoulder Humeral Tray (K113069)

Biomet Comprehensive Reverse Shoulder Mini Baseplate (K120121)

Biomet Comprehensive Reverse Shoulder – Titanium Glenosphere (K131353)

Biomet Comprehensive Augmented Glenoid Components, Comprehensive Standard Baseplate, Comprehensive Mini Baseplate (K172502)

Biomet Comprehensive Reverse Shoulder System (K181611)

Intended Use / Indications:

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.

Device Description:

The Inset Reverse Total Shoulder System is intended for total shoulder replacement in a reverse shoulder configuration. Unlike traditional total shoulder replacement, a reverse shoulder employs a ball for articulation on the glenoid side of the joint and a polyethylene bearing surface on the humeral side of the joint.

For the Inset Reverse Total Shoulder System, a Glenosphere Baseplate is attached to natural bone on the glenoid side of the joint with a Central Compression Screw and Peripheral Screws. The baseplate includes a female taper to mate with the chosen Glenosphere. Glenoid baseplate components are indicated for a press-fit cement-less application with the addition of screw fixation. The chosen Humeral Bearing is attached

to the Humeral Tray and the assembly is attached to the Humeral Stem (K173824) to complete the humeral side of the joint. Humeral stems are indicated for press-fit un-cemented use or for use with bone cement.

The material used in the manufacture of the humeral stem, glenoid baseplate, modular tray, compression screw, and supplementary screws are titanium alloy according to ASTM F136.

The humeral stem and the glenoid baseplate have a proximal porous coating of commercially pure titanium according to ASTM F67. The glenosphere is available in cobalt-chromium (CoCr) alloy, per ASTM F1537. The humeral bearing is manufactured from ultrahigh molecular weight polyethylene (UHMWPE) according to ASTM F648. The instruments are manufactured from stainless steel and acetal copolymer.

Summary of Technological Characteristics and Substantial Equivalence to the Predicate Device:

The Inset Reverse Total Shoulder System is substantially equivalent to the predicate device in that both are total shoulder systems intended for a reverse configuration, both are indicated for use in primary or revision total shoulder replacement, and both are indicated for use with grossly rotator cuff deficient joints with severe arthropathy.

Both the Inset Reverse Total Shoulder System and the predicate device are manufactured from Ti6Al4V alloy, CoCrMo alloy, and UHMWPE.

Both the Inset Reverse Total Shoulder System and the predicate device glenoid baseplates are intended for cementless application with the addition of screw fixation.

Both the Inset Reverse Total Shoulder System and the predicate device humeral stems are intended for press-fit or cement fixation.

Both the Inset Reverse Total Shoulder System and the predicate device implant components are similarly implanted; both humeral stems, press-fit or cemented, are assembled to trays with polyethylene liners that articulate with a metal glenosphere attached to a glenoid baseplate that is fixed to the glenoid with bone screws. The

baseplate of the predicate device is positioned off the bone when implanted, whereas the Inset Reverse Total Shoulder System Glenoid Baseplate is inset in the bone.
The implant components are offered in comparable sizes.
The design differences do not raise new issues of safety or effectiveness and are supported by performance testing.

Non-Clinical Testing:

Non-clinical testing has been performed on the Inset Reverse Total Shoulder System as follows:

- Glenoid Baseplate – Glenosphere Displacement and Cyclic Fatigue Test
- Glenoid Baseplate - Glenosphere Rotational Torque Test
- Glenoid Baseplate - Glenosphere Taper Axial Strength Test
- Glenosphere Modular Connection – Fretting Corrosion Test
- Humeral Stem – Tray - Bearing Cyclic Fatigue Test
- Humeral Stem - Humeral Tray Taper Strength Test
- Humeral Bearing – Humeral Tray Offset Pull Out Disassembly
- Humeral Bearing – Humeral Tray Axial Disassembly
- Humeral Bearing – Humeral Tray Torque Out Disassembly
- Driving Torque Testing
- Torsional Properties Testing
- Cadaver Study
- Range of Motion Analysis

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Inset Reverse Total Shoulder System to the predicate device.

Summary of Technologies / Substantial Equivalence:

Based on the information presented in this submission, Shoulder Innovations concludes that the Inset Reverse Total Shoulder System is substantially equivalent to the predicate

device in regard to indications, materials and design and does not raise new questions in regard to safety and effectiveness of the device.