March 11, 2022

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

Re: K213615
Trade/Device Name: Shoulder Innovations 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: PKC
Dated: February 3, 2022
Received: February 9, 2022

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,

Lixin Liu, Ph.D.
Acting 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)*

K213615

Device Name

Shoulder Innovations Total Shoulder System

Indications for Use *(Describe)*

The Shoulder Innovations Total Shoulder System with Humeral Stemless is intended for use as an orthopedic implant for total shoulder arthroplasty to treat severely painful and/or disabled joint resulting from osteoarthritis or traumatic arthritis.
The Shoulder Innovations Total Shoulder System components are intended for single use only.
The Humeral Stemless components are indicated for press-fit, un-cemented use. The glenoid component is intended for cemented fixation only.

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: November 8, 2021

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

Contact: Don Running
Vice President – R&D
Shoulder Innovations
(574) 253-1133
don@genesisinnovationgroup.com

Proprietary Name: Shoulder Innovations 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: PKC

Review Panel: Orthopedic

Predicate Device: K143552 – Tornier Simpliciti Total Shoulder System

Reference Device: K173824 – Shoulder Innovations Humeral Short Stem System

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, as the humeral head acts as the collar, and manufactured from Titanium Alloy (Ti-6AL-4V) conforming to ASTM F136 with fins to provide rotational stability and are coated with a rough, porous coating. The stems have a female Morse-type taper to interface with the modular humeral heads. 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) with a pegged design intended for cemented fixation.

This submission adds Humeral Stemless Implants to the Shoulder Innovations Total Shoulder System. The Humeral Stemless Implants are similar to the previously cleared humeral short stems (K173824), except that the Humeral Stemless Implants do not include the stem. The Humeral Stemless Implants have fins to provide rotational stability and a female Morse-type taper to interface with modular humeral heads, identical to the humeral short stems (K173824). The Humeral Stemless Implants are manufactured from Titanium Alloy (Ti-6Al-4V) conforming to ASTM F136 with a proximal porous coating of commercially pure titanium according to ASTM F67.

The Humeral Stemless Implants are for press-fit, uncemented use.
All Humeral Stemless Implants are compatible with the previously cleared Total Shoulder System humeral heads (K173824) and previously cleared Total Shoulder System glenoid components (K111596 and K192365).

Intended Use / Indications:
The Shoulder Innovations Total Shoulder System with Humeral Stemless is intended for use as an orthopedic implant for total shoulder arthroplasty to treat severely painful and/or disabled joint resulting from osteoarthritis or traumatic arthritis.

The Shoulder Innovations Total Shoulder System components are intended for single use only.

The Humeral Stemless components are indicated for press-fit, un-cemented use. The glenoid component is intended for cemented fixation only.

Non-Clinical Testing:

The Humeral Stemless Implants were evaluated to demonstrate substantial equivalence to the predicate stemless device. Lever out, pull out, torque out and fatigue testing were performed on the Humeral Stemless Implants.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Shoulder Innovations Total Shoulder System Humeral Stemless Implants to the predicate device.

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

Shoulder Innovations Humeral Stemless Implant is substantially equivalent to the predicate device in that both the predicate and proposed device are similar in indications for use and technological characteristics. The predicate and proposed device carry the same intended use, namely they are both orthopedic implants intended to treat severely painful and/or disabled joint resulting from osteoarthritis or traumatic arthritis. Both the predicate and proposed device utilize a similar technological characteristics, specifically the stemless humeral design that is contained entirely within the metaphysis. Additional technological characteristic similarities include overall implant length, base materials and porous coating, and bone integration mode of action utilizing the porous coating.

Shoulder Innovations Humeral Stemless Implant is similar to the reference device in that both the reference and proposed device are similar in indications for use and technological characteristics. The reference device and proposed device carry a similar indication for use as they are both intended for use with the Shoulder Innovations Total Shoulder to treat a disabled joint resulting from degenerative or traumatic joint disease. The reference device and proposed device carry similar technological characteristics, including the device design, such as the similar fin shape, body shape and curvature, proximal diameters, and interface connection with humeral head; identical materials, such as the base material and

porous coating materials and manufacturer; and bone integration mode of action utilizing the porous coating.

Conclusions:

Based on the information presented in this submission, Shoulder Innovations concludes that the Shoulder Innovations Total Shoulder System is substantially equivalent to the predicate device in regard to indications, materials and design and do not raise different questions in regard to safety and effectiveness of the device, nor are there new technological characteristics.