November 29, 2019

Shoulder Innovations Inc
Don Running
VP R&D
13827 Port Sheldon Street
HOLLAND, MI 49424

Re: K192365
Trade/Device Name: Shoulder Innovations 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, MBF, HSD
Dated: October 25, 2019
Received: November 1, 2019

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,

for

Michael Owens
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K192365

Device Name
Shoulder Innovations Total Shoulder System

Indications for Use *(Describe)*
The Shoulder Innovations Total Shoulder System 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. avascular necrosis of the humeral head.

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

The 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**: August 27, 2019

**Submitter**: Shoulder Innovations
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

**Classification:** 21 CFR Section 888.3650 – Shoulder joint metal/polymer non-constrained cemented prosthesis; Class II
Product Code: KWT

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

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

21 CFR Section 888.3690 – Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis; Class II
Product Code: HSD

**Substantially Equivalent Devices:** K111596 – Shoulder Innovations Total Shoulder System (glenoid modification)
K173824 - Shoulder Innovations Humeral Short Stem System (humeral modification)

**Reference Device:** K121220 – Exactech Equinoxe UHMWPE 16° Posterior Augmented Pegged Glenoids

**Intended Use / Indications:**

The Shoulder Innovations Total Shoulder System 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. avascular necrosis of the humeral head.

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

The 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.

The indications for use are unchanged from K173824 for the Total Shoulder 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 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 multi-pegged design intended for cemented fixation only.

**Proposed Modification:**

The subject of this submission is a line extension to add the Augmented Glenoids to the Shoulder Innovations Total Shoulder System. The Augmented Glenoids are almost identical to the previously cleared glenoid component (K111596) except for an angled articular surface, creating the augmented glenoid. The Augmented Glenoids are available in both 5° and 10° variants. The Augmented Glenoids are manufactured from UHMWPE conforming to ASTM F648, which is the same material as the previously cleared glenoid components, utilizing the same manufacturing processes. The Augmented Glenoids are available in multiple widths.

All Shoulder Innovations Total Shoulder System Augmented Glenoids are compatible with the previously cleared Total Shoulder System humeral components (K102670 and K173824).

**Non-Clinical Testing:**

The Augmented Glenoids were evaluated to demonstrate substantial equivalence to the predicate devices. Testing was performed in accordance with ASTM F2028-17, *Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation*. Cadaver testing of the Augmented Glenoids was also performed. The test results demonstrated that the Augmented Glenoids are adequate for their intended use.

**Clinical Testing:**

Clinical testing was not necessary to demonstrate substantial equivalence of the Shoulder Innovations Total Shoulder System Augmented Glenoids to the predicate devices.

## Predicate Device Comparison:

| Property or Characteristic | Shoulder Innovations Total Shoulder System Glenoid Component (K111596) | Shoulder Innovations Total Shoulder System Augmented Glenoids (Current Submission) |
|---|---|---|
| *Material* | UHMWPE | Same as K111596 |
| *Articulating Surface Geometry* | Concave with modified radius of curvature | Same as K111596 |
| *Minimum Poly Thickness* | 3.3 mm | Same as K111596 |
| *Perimeter Geometry* | Ellipse with sides trimmed at an acute angle | Ellipse with sides trimmed parallel |
| *Angle of articular surface* | None | 5° or 10° |
| *Provided Sterile* | Yes | Same as K111596 |
| *Fixation Method* | Cemented Only | Same as K111596 |

## Summary of Technologies / Substantial Equivalence:

The Shoulder Innovations Augmented Glenoids are substantially equivalent to the Shoulder Innovations Total Shoulder System glenoid components in regard to indications for use, material and design. The angling of the articular surface of the glenoid to create the Augmented Glenoids does not raise new questions in regard to safety and effectiveness of the device, nor are there new technological issues.