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

October 23, 2018

Re: K173824
Trade/Device Name: Humeral Short Stem System
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBF, KWT, KWS, HSD
Dated: September 12, 2018
Received: September 14, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel S. Ramsey -S
2018.10.23 16:48:03 -04'00'

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K173824

Device Name
Humeral Short Stem 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
Pursuant to 21 CFR 807.92c

Date Prepared:	September 12, 2018
Submitted By:	Shoulder Innovations, LLC 13827 Port Sheldon St. Holland, MI 49424
Contact:	Don Running VP-R&D 574-253-1133 don@genesisinnovationgroup.com
Proprietary Name:	Humeral Short Stem System
Common Name:	Shoulder Prosthesis
Classification:	21 CFR Section 888.3670 – Shoulder joint metal/ polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis Product Code: MBF 21 CFR Section 888.3650 – Shoulder joint metal/polymer non-constrained cemented prosthesis. Product Code: KWT 21 CFR Section 888.3660 – Shoulder joint metal/polymer semi-constrained cemented prosthesis. Product Code: KWS 21 CFR Section 888.3690 – Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis. Product Code: HSD
Substantially Equivalent Device:	K060692, Biomet Comprehensive® Primary Shoulder Stems

Device Description:

The Shoulder Innovations Humeral Short Stem System consists of modular humeral stems and heads and articulates with the Shoulder Innovations glenoid component (K111596). 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.

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.

Predicate Device Comparison:

Humeral Stem Component

Feature	**Biomet Comprehensive Primary Shoulder Stems (K060692)**	**Proposed Device Shoulder Innovations Humeral Short Stem System**	**SE?**
Distal Stem Diameters	5.75 mm (Labeled 4mm)	5.75 mm	Yes
Stem Lengths	72 mm	70 mm	Yes
Stem Geometry	Tapered circular	Tapered circular	Yes
Collar	Collarless	Collarless	Yes

Feature	Biomet Comprehensive Primary Shoulder Stems (K060692)	Proposed Device Shoulder Innovations Humeral Short Stem System	SE?
Modular system	Female Morse-type taper	Female Morse-type taper	Yes
Bone Integration	Porous Coating	Porous Coating	Yes
Neck Angle	135°	132.5°	Yes
Fixation	Press-fit or Cemented	Press-fit or Cemented	Yes
Material	Titanium Alloy	Titanium Alloy	Yes
Sterility	Gamma Irradiated	Gamma Irradiated	Yes

Humeral Head Component

Feature	Biomet Comprehensive Primary Shoulder Stems (K060692)	Proposed Device Shoulder Innovations Humeral Short Stem System	SE?
Head Diameters	38, 42, 46, 50, 54, 58mm	40mm, 44mm, 48mm, 52mm, and 56mm	Yes
Head Heights	18mm – 27mm	15mm – 24mm	Yes
Configurations	Standard and Offset	Standard and Offset	Yes
Geometry	Solid semi-sphere	Solid semi-sphere	Yes
Modular system	Male Morse-type taper	Male Morse-type taper	Yes
Material	CoCr	CoCr	Yes
Sterility	Gamma Irradiated	Gamma Irradiated	Yes

Non-Clinical Testing:

Performance testing was performed on the Shoulder Innovations Humeral Stem System. The modular humeral components were tested per ASTM F2009 *Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses*. Fatigue testing was also performed on the humeral components.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Shoulder Innovations Humeral Short Stem System to the predicate device.

Summary of Substantial Equivalence:

The results of non-clinical testing and comparative analysis demonstrate that the design, function, intended use, and indications for use of the Shoulder Innovations Humeral Short Stem System is substantially equivalent to the predicate device.