April 21, 2022

Depuy Ireland UC
℅ Russ Parrott
VP of Research and Development
Ignite Orthopedics LLC
700 Park Avenue Suite F
Winona Lake, Indiana 46590

Re: K212737
Trade/Device Name: INHANCE™ Reverse 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, KWT, KWS, PAO, HSD
Dated: August 27, 2021
Received: August 30, 2021

Dear Russ Parrott:

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 -S

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)*
K212737

Device Name
INHANCE™ Reverse Shoulder System

Indications for Use *(Describe)*

Anatomic Total Shoulder or Hemi-Shoulder

The INHANCE SHOULDER SYSTEM with the humeral stemless anchor is intended for use in anatomic total shoulder replacement procedures to address the following:
- Osteoarthritis
- Post-traumatic arthrosis
- Focal avascular necrosis of the humeral head
- Previous surgeries of the shoulder that do not compromise the fixation

The INHANCE SHOULDER SYSTEM with a humeral stem is intended for use in anatomic total or hemi-shoulder replacement procedures to address the following:
- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
- Rheumatoid arthritis.
- Revision where other devices or treatments have failed.
- Correction of functional deformity.
- Fractures of the humeral head (with Short Humeral Stems)
- Fractures of the proximal humerus, where other methods of treatment are deemed inadequate (with Standard or Long Stems)
- Difficult clinical management problems where other methods of treatment may not be suitable or may be inadequate.

Fixation Methods
The humeral stems are intended for cemented or cementless use. The humeral stemless anchor is intended for cementless use. The glenoid is intended for cemented use only.

Reverse Total Shoulder

The INHANCE SHOULDER SYSTEM Reverse Total Shoulder with a humeral stem is indicated for primary, fracture or revision total reverse shoulder replacement procedures to address the following. The system is indicated for use in patients whose shoulder joint has a gross rotator cuff deficiency. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary. The system is also indicated for conversion from an anatomic to reverse shoulder prosthesis without the removal of a well-fixed INHANCE humeral stem.
- A severely painful, disabling, arthritic joint
- Fractures of the humeral head (with Short Humeral Stems)
- Fractures of the proximal humerus (with Standard or Long Stems)
- Revisions of previously failed shoulder joint replacements

Fixation Methods
The humeral stem is intended for cemented or cementless use. The glenoid baseplate components are intended for cementless application with the addition of screw 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.

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510(k) Summary

Prepared: March 18, 2022

Submitter: DePuy Ireland UC
Loughbeg
Ringaskiddy
CO. CORK Munster, IE

Contact: Russ Parrott
Chief Technology Officer
Phone: 574.527.2864
russ.parrott@igniteorthopedics.com

Proprietary Name: INHANCE™ Reverse Shoulder System

Common Name: Reverse Shoulder Arthroplasty System

Classification: Shoulder joint metal/polymer semi-constrained cemented prosthesis; (21 CFR §888.3660); Class II

Shoulder Joint, Metal/Polymer/Metal, Non-Constrained or Semi-Constrained, Porous Coated, Uncemented Prosthesis (21 CFR §888.3670); Class II

Prosthesis, Shoulder, Non-Constrained, Metal/Polymer, Cemented (21 CFR §888.3650); Class II

Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer, Cemented (21 CFR §888.3660); Class II

Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer + Additive, Cemented (21 CFR §888.3660); Class II

Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented (21 CFR §888.3690); Class II

Product Codes: PHX, MBF, KWT, KWS, PAO, HSD

Predicate Devices:

K193373 (Primary) - Comprehensive Reverse Shoulder; Biomet, Inc.
K202716 - Ignite Anatomic Shoulder System; Ignite Orthopedics LLC
K060692 - Comprehensive Primary Shoulder Stems, Biomet, Inc.

Reference Devices:

K181611 - Comprehensive Reverse Shoulder System; Biomet, Inc.
K130048 - Reverse Shoulder Prosthesis Monoblock; ENCORE Medical, L.P.
K172351 - AltiVate Reverse Humeral Stem, AltiVate Reverse Small Spacer, Altivate Reverse, Small Hemi-Adapter, AltiVate Reverse, Small Socket Insert; ENCORE Medical, L.P.
K130050 - Titan Reverse Shoulder System; Ascension Orthopedic
K161742 - Aequalis PerFORM Reversed, Aequalis PerFORM+ Reversed Glenoid; Tornier, Inc.
K183077 - Delta XTEND Reverse Shoulder System; DePuy (Ireland)
K062250 - Delta XTEND Reverse Shoulder System; DePuy Orthopaedics, Inc.
K120174 - Delta XTEND Reverse Shoulder; DePuy France
K081620 - Modification to Delta XTEND Reverse Shoulder System; DePuy Orthopaedics, Inc.
K071379 - Delta XTEND Reverse Shoulder Modular Stem; DePuy Orthopaedics, Inc.
K122698 - Aequalis Ascend Flex Shoulder System; Tornier, Inc.
K052906 - Zimmer Trabecular Metal Reverse Shoulder System; Zimmer, Inc.

Device Description:

The INHANCE^{TM} SHOULDER SYSTEM with a humeral stemless anchor is intended for use in anatomic total shoulder replacement procedures.

The INHANCE SHOULDER SYSTEM with a humeral stem is intended for use in anatomic total, reverse total, or hemi-shoulder replacement procedures.

The Anatomic Total Shoulder Prosthesis consists of individually packaged implants: a metal humeral stem or humeral stemless anchor (titanium alloy), an offset taper adapter (titanium alloy),

a humeral head (cobalt-chromium) in combination with a Cross-linked, Vitamin E Ultra High Molecular Weight Polyethylene (Cross-linked, VE UHMWPE) glenoid.

The Reverse Total Shoulder Prosthesis consists of individually packaged implants: a metal humeral stem (titanium alloy), a shell (titanium alloy), a liner (Cross-linked, VE UHMWPE) in combination with a glenosphere (cobalt-chromium), baseplate (titanium alloy), peripheral screws (titanium alloy), and either a central screw (titanium alloy) or a central post (titanium alloy).

The Anatomic Hemi-Shoulder Prosthesis consists of individually packaged implants: a metal humeral stem (titanium alloy) an offset taper adapter (titanium alloy), a humeral head (cobalt-chromium) (no glenoid component associated).

Intended Use/Indications For Use:

Anatomic Total Shoulder or Hemi-Shoulder

The INHANCE SHOULDER SYSTEM with the humeral stemless anchor is intended for use in anatomic total shoulder replacement procedures to address the following:

- Osteoarthritis
- Post-traumatic arthrosis
- Focal avascular necrosis of the humeral head
- Previous surgeries of the shoulder that do not compromise the fixation

The INHANCE SHOULDER SYSTEM with a humeral stem is intended for use in anatomic total or hemi-shoulder replacement procedures to address the following:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
- Rheumatoid arthritis.
- Revision where other devices or treatments have failed.
- Correction of functional deformity.
- Fractures of the humeral head (with Short Humeral Stems)
- Fractures of the proximal humerus, where other methods of treatment are deemed inadequate (with Standard or Long Stems)
- Difficult clinical management problems where other methods of treatment may not be suitable or may be inadequate.

Fixation Methods

The humeral stems are intended for cemented or cementless use. The humeral stemless anchor is intended for cementless use. The glenoid is intended for cemented use only.

Reverse Total Shoulder

The INHANCE SHOULDER SYSTEM Reverse Total Shoulder with a humeral stem is indicated for primary, fracture or revision total reverse shoulder replacement procedures to address the following. The system is indicated for use in patients whose shoulder joint has a gross rotator cuff deficiency. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary. The system is also indicated for conversion from an anatomic to reverse shoulder prosthesis without the removal of a well-fixed INHANCE humeral stem.

- A severely painful, disabling, arthritic joint
- Fractures of the humeral head (with Short Humeral Stems)
- Fractures of the proximal humerus (with Standard or Long Stems)
- Revisions of previously failed shoulder joint replacements

Fixation Methods

The humeral stem is intended for cemented or cementless use. The glenoid baseplate components are intended for cementless application with the addition of screw fixation.

Summary of Technologies/Substantial Equivalence:

The implant and associated instruments within the INHANCE™ Reverse Shoulder System are substantially equivalent to the predicate devices in terms to its intended use and indications, material, design, sizes, and mechanical properties. Differences between the subject device system and the predicate device systems do not raise different questions of safety and effectiveness.

Non-Clinical Testing:

The INHANCE™ Reverse Shoulder System underwent non-clinical testing and analyses to support a determination of substantial equivalence to the predicate device. The following were completed:

Range of Motion (RoM) Evaluation

An evaluation was conducted to ensure the RoM of the worst-case subject device components meet established specifications per ASTM F1378. The RoM targets were met.

Construct Fatigue Testing

Construct fatigue testing was performed per ASTM F1378. The acceptance criteria were met.

Construct Loosening and Disassociation

The INHANCE™ Reverse Shoulder System was evaluated for loosening and disassociation per ASTM F2028-17. The acceptance criteria were met.

Biocompatibility Assessments

The contact classification for the subject devices is Implant, Bone/Tissue with permanent contact (>30 days). A Biocompatibility Assessments was completed and provided per ISO 10993-1 and FDA Guidance Document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The devices were found to be biocompatible.

Porous Structure Characterization

The porous structure used for the subject device is identical to the porous structure that was applied to the implants cleared under K202716 (Ignite Anatomic Shoulder System) and K203108 (Ignite Stemless Anatomic Shoulder System).

Characterization of VE-UHMWPE

The Vitamin E Ultra High Molecular Weight Polyethylene (Cross-linked, VE UHMWPE) material used for the Liners of the INHANCE™ Reverse Shoulder is identical to the VE UHMWPE material that was used on the devices cleared under K202716 (Ignite Anatomic Shoulder System). The material was fully characterized per FDA Guidance, "Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices-Guidance for Industry and Food and Drug Administration Staff" in K202716.

Evaluation of Wear Rate

Wear testing of the Vit-E UHMWPE liners was completed on a joint simulator under pristine and abrasive conditions. Prior to wear testing, the liners were accelerated aged per ASTM F2003. The resulting wear rate was lower than that of a predicate device. The acceptance criteria were met. Micro-CT assessment of wear features on the humeral liners was conducted following abrasive wear testing.

MRI Compatibility

Quantitative data was obtained to inform Magnetic Resonance Imaging (MRI) Conditional Labeling through the following evaluations:

- Force: Static Magnetic Field Induced Displacement Force per ASTM F2052-15
- Torque: Static Magnetic Field Induced Torque per ASTM F2213-17
- Heating: Radiofrequency field (RF) induced heating per ASTM F2182-19e2
- Image Quality: Susceptibility induced image artifacts per ASTM F2119-07

Shelf Life Evaluation

A shelf life evaluation per ISO 11607-1 and ISO 11607-2 was completed on the packaging materials that make up the sterile barrier. A five-year shelf life was established based on the resultant data.

Sterilization Validation

Sterilization validation was completed using the VDmax method specified in ISO 11137-1 and ISO 11137-2. The Sterility Assurance Level (SAL) was found to be 10^{-6}.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the INHANCE™ Reverse Shoulder System to the predicate devices.

Conclusion:

A comparison of the subject and predicate devices, including comparison of the intended use, technological characteristics, and non-clinical testing results has demonstrated that the subject devices have a safety and effectiveness profile equivalent to that of the predicate devices. Thus, the subject devices are substantially equivalent to the predicate devices.