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

November 13, 2023

Re: K230831
Trade/Device Name: INHANCE Shoulder System Convertible Glenoid Inserts, INHANCE Convertible Glenoid
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, PAO, PKC, HSD
Dated: October 12, 2023
Received: October 16, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

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

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2023.11.13 10:14:55 -05'00'

for: Farzana Sharmin, PhD
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)*
K230831

Device Name
INHANCE™ Convertible Glenoid

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 humeral head and proximal humerus, where other methods of treatments 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 stem is intended for cemented or cementless use. The humeral stemless anchor is intended for cementless use. The anatomic glenoid and anatomic hybrid glenoid are intended for cemented use only. The baseplate components of the convertible glenoids are intended for cementless application with the addition of screw fixation. When a convertible glenoid liner is used, the baseplate is indicated for use with a central screw and three peripheral locking screws that are 25mm or greater in length. The peripheral non-locking screws, peripheral posts and central posts are not indicated for use with the convertible glenoid.

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 humeral head and 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. When a peripheral post is used, the baseplate is indicated for use with a central screw and two peripheral locking screws that are 25mm or greater in length. The peripheral non-locking screws and central posts are not indicated for use with the peripheral post.

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

Prepared:	November 9, 2023
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™ Convertible Glenoid
Common Name:	Shoulder Arthroplasty System
Classification:	Shoulder Joint, Metal/Polymer/Metal, Non-Constrained or Semi-Constrained, Porous Coated, Uncemented Prosthesis (21 CFR §888.3670); Class II Shoulder joint metal/polymer non-constrained cemented prosthesis (21 CFR §888.3650); Class II Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CER §888.3660); Class II Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (21 CER §888.3690); Class II

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

Predicate Devices: K202716 (Primary) - INHANCE Anatomic Shoulder System; DePuy Ireland UC (formerly Ignite Anatomic Shoulder System; Ignite Orthopedics LLC)
K203108 – INHANCE (Ignite) Stemless Anatomic Shoulder System; DePuy Ireland UC
K212737 – INHANCE Reverse Shoulder System; DePuy Ireland UC
K130390 – Comprehensive Convertible Glenoid; Biomet Manufacturing Corporation

Reference Devices: K212933 – INHANCE Hybrid Anatomic Glenoid; DePuy Ireland UC
K182039 – Arthrex Univers Revers Porous Coated Baseplate and Universal Glenoid Inlay; Arthrex
K092122 – Global Shoulder Steptech Anchor Peg Glenoid; DePuy Orthopaedics
K113254 – SMR Modular Glenoid; Limacorporate S.P.A

Device Description:
The INHANCE™ Convertible Glenoid system consists of a Baseplate with minor modifications compared to the previously cleared Baseplate in K212737 and a poly insert that locks atop the Baseplate to allow for an anatomic procedure. The Convertible Glenoid Insert implants are offered in four sizes: Small (24.0mm), Medium (26.5mm), Large (29.0mm), and X-Large (31.5mm). The Convertible Glenoid Insert implants consist of a Cross-linked, Vitamin E Ultra High Molecular Weight Polyethylene (Cross-linked, VE UHMWPE) articulation surface and an interrupted fixation ring along with a finned central fixation post to facilitate poly locking to the Convertible Glenoid Baseplate.

The INHANCE™ Convertible Glenoid Insert Implants have a lateral surface that is concave and designed to articulate with the Humeral Heads from the INHANCE Anatomic Stemmed and Stemless Shoulder Systems that are indicated for use in total shoulder arthroplasty.

The INHANCE™ Convertible Glenoid Baseplates, previously cleared in K212737, were modified to provide for a means of mechanical fixation between the Convertible Glenoid Inserts and Baseplates.

The INHANCE Convertible Glenoid implants are compatible with the implants and instruments previously cleared for use in the INHANCE Anatomic Shoulder System (K202716), the INHANCE Stemless Anatomic Shoulder System (K203108), and the INHANCE Reverse Shoulder System (K212737).

Note: When using a Convertible Glenoid Insert, the INHANCE Glenoid Baseplate is only indicated for use with a Central Screw and Peripheral Locking Screws that are 25mm or greater in length. Non-Locking Screws and Peripheral Posts are not indicated for use with the Convertible Glenoid.

This submission also includes an update of the Reverse Total Shoulder replacement Indications for Use to add clarity of intended use of the baseplate screws when a Peripheral Post is used with the baseplate.

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 humeral head and proximal humerus, where other methods of treatments 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 stem is intended for cemented or cementless use. The humeral stemless anchor is intended for cementless use. The anatomic glenoid and anatomic hybrid glenoid are intended for cemented use only. The baseplate components of the convertible glenoids are intended for cementless application with the addition of screw fixation. When a convertible glenoid liner is used, the baseplate is indicated for use with a central screw and three peripheral locking screws that are 25mm or greater in length. The peripheral non-locking screws, peripheral posts and central posts are not indicated for use with the convertible glenoid.

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 humeral head and proximal humerus (with Standard or Long Stems)
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Fixation Methods

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Summary of Technologies/Substantial Equivalence:

The INHANCE™ Convertible Glenoid Insert Implants are substantially equivalent to the primary predicate device in terms of 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.

In summary, the subject device and the INHANCE Shoulder glenoid predicate device (K202716) are substantially equivalent based on the following same technological characteristics:

- Intended to be used for total shoulder arthroplasty.
- Material (AO-HXLPE).
- Circular shape insert.
- Articulating geometry and surface finishes of the Glenoid.
- Glenoid size range (24mm to 31.5mm) is within the predicate's size range (21.5mm to 31.5mm).
- Humeral Head implants that articulate with the Convertible Glenoid Liner.
- Backside bone preparation is Spherical Reaming.
- Gamma sterilized (SAL 10^{-6}), single-use.
- Packaging system and shelf-life.

The following technological differences exist between the subject and predicate devices. Those characteristics are equivalent to the additional predicate and reference devices:

- Differences in glenoid insert geometry.
- Polyethylene Insert is fixed into Metal Baseplate by press-fit.

Non-Clinical Testing:

The INHANCE™ Convertible Glenoid 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.

Biocompatibility Assessments

The contact classification for the subject devices is Implant, Bone/Tissue with permanent contact (>30 days). A Biocompatibility Assessment 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 and K203108.

Characterization of AO-HXLPE

The antioxidant highly crosslinked UHMWPE (AO-HXLPE) was fully characterized and conforms to ASTM F2695. The Vitamin E Ultra High Molecular Weight Polyethylene (Cross-linked, VE UHMWPE) material used for the INHANCE™ Convertible Glenoids is identical in base resin, blending concentration of antioxidant, and crosslinking irradiation dose to the VE UHMWPE material that was used on the devices cleared under K202716.

Evaluation of Glenoid Wear Rate

An engineering justification demonstrated that the subject device does not represent a new worst-case for wear of the articulating surfaces when compared to the predicate devices.

Dynamic Evaluation of Convertible Glenoid Loosening/Disassociation

The INHANCE™ Convertible Glenoid Implants were tested according to ASTM F2028. The acceptance criteria were met.

Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear

The INHANCE™ Convertible Glenoid Implants were tested according to ASTM F1829. The acceptance criteria were met.

Glenoid Fatigue Resistance Evaluation

A mechanical evaluation was conducted to study the dissociation of the VE XLPE Glenoid Inserts and the Ti6Al4V Baseplate. The acceptance criteria were met.

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 device materials and the packaging materials that make up the sterile barrier and device materials. 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™ Convertible Glenoid Implants 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 device has a safety and effectiveness profile equivalent to that of the predicate device. Thus, the subject device is substantially equivalent to the predicate device.