Depuy Ireland UC
% Russ Parrott
Chief Technology Officer
Ignite Orthopedics LLC
700 Park Avenue Suite F
Winona Lake, Indiana 46590

June 8, 2022

Re: K212933
Trade/Device Name: INHANCE™ Hybrid Anatomic Glenoid Implant
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, HSD
Dated: May 9, 2022
Received: May 10, 2022

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,

For Jiping Chen, M.D., Ph.D., M.P.H.
Acting Division 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)*
K212933

Device Name
INHANCE™ Hybrid Anatomic Glenoid Implant

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 (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.

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.**

## 510(k) Summary

**Prepared:** June 6, 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™ Hybrid Anatomic Glenoid Implant

**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

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 CER §888.3660); Class II

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

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

**Predicate Devices:**
K202716 - Ignite Anatomic Shoulder System; Ignite Orthopedics LLC

K060694 - Modular Hybrid Glenoid, Biomet Manufacturing Corp.

**Reference Devices:** K052472 - DePuy Global Shoulder Crosslink Glenoid, DePuy Orthopedics, Inc.

K212737 - INHANCE Reverse Shoulder System, DePuy Ireland UC

**Device Description:**

The INHANCE™ Hybrid Anatomic Glenoid Implants are offered in five sizes: X-Small (21.5mm), Small (24.0mm), Medium (26.5mm), Large (29.0mm), and X-Large (31.5mm). The Glenoid Implants consist of a Cross-linked, Vitamin E Ultra High Molecular Weight Polyethylene (Cross-linked, VE UHMWPE) articulation surface and fixation ring along with an additively manufactured Ti-6Al-4V (titanium alloy) central fixation post.

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

**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 (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.

**Summary of Technologies/Substantial Equivalence:**

The INHANCE™ Hybrid Anatomic Glenoid Implants are substantially equivalent to the predicate device in terms of their intended use and indications, material, design, sizes, and mechanical properties. While the predicate device is composed entirely of cross-linked VE UHMWPE machined from ram extruded bar stock, the cross-linked VE UHMWPE body of the INHANCE Hybrid Glenoid Implants are direct compression molded into an additively manufactured Ti-6Al-4V central porous post. Differences between the subject device system and the predicate device system do not raise different questions of safety and effectiveness.

**Non-Clinical Testing:**

The INHANCE™ Hybrid Anatomic Glenoid Implants 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 device 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 subject device was 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 (Crosslinked, VE UHMWPE) material used for the INHANCE Hybrid Anatomic 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*

The direct compression molded articulating surfaces on the INHANCE Hybrid Anatomic Glenoid Implants do not present a new worst case for wear testing when compared to articulating surfaces of the same geometry and material that are machined from ram extruded bar stock.

*Glenoid Loosening Testing*

The INHANCE™ Hybrid Anatomic Glenoids were tested according to ASTM F2028. The acceptance criteria were met.

*Glenoid Torsional Resistance Testing*

The INHANCE™ Hybrid Anatomic Glenoids were subjected to static torsional resistance testing. The acceptance criteria were met.

*Axial Pull-out Testing*

The INHANCE™ Hybrid Anatomic Glenoids were subjected to axial pullout testing. The acceptance criteria were met.

*Ti6Al4V Post Disassembly Evaluation*

A mechanical evaluation was conducted to study the risk of dissociation of the Ti6Al4V Post and the VE XLPE Glenoid body. 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 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™ Hybrid Anatomic Glenoid Implants to the predicate device.

**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.