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

August 31, 2022

Re: K221467
Trade/Device Name: INHANCE™ Reverse Glenoid Peripheral Posts
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, MBF, PAO
Dated: August 24, 2022
Received: August 25, 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 Victoria Lilling, M.D.
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)*
K221467

Device Name
INHANCE™ Reverse Glenoid Peripheral Posts

Indications for Use *(Describe)*

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.

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: August 30, 2022

Submitter:
Ignite Orthopedics LLC
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Suite F
Winona Lake, IN 46590

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

Proprietary Name: INHANCE™ Reverse Glenoid Peripheral Posts

Common Name: Reverse Shoulder Arthroplasty System

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

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

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

Product Codes: PHX, MBF, PAO

Predicate Devices: K212737 (Primary) - INHANCE Reverse Shoulder System, DePuy Ireland UC

K202611 – Catalyst OrthoScience R1 Reverse Shoulder System; Catalyst OrthoScience, Inc.

Reference Devices: K202716 – Ignite Anatomic Shoulder System;
Ignite Orthopedics LLC

K183077 – Delta XTEND Reverse Shoulder System;
DePuy (Ireland)

Device Description:

The INHANCE REVERSE SHOULDER SYSTEM with Glenoid Peripheral Posts is intended for use in reverse total replacement procedures.

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), peripheral posts (titanium alloy), and either a central screw (titanium alloy) or a central post (titanium alloy).

The INHANCE REVERSE SHOULDER SYSTEM includes Peripheral Posts that are offered in 4MM, 6MM and 8MM lengths. The Peripheral Posts can be simply prepared for, and placed through, one of the peripheral holes of the Baseplate to increase contact area and aid in stability. This versatile option allows for interoperative flexibility and simple preparation to address various glenoid morphologies.

Note(s):

- When using a Peripheral Post implant, the INHANCE Reverse Shoulder System is only indicated for use with a Central Screw and Peripheral Locking Screws that are 25mm or greater in length.
- The Peripheral Post implants are only indicated for use in anterior, posterior, and superior glenoid defects.

Intended Use / Indications for Use:

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.

Summary of Technologies/Substantial Equivalence:

The subject INHANCE Reverse Glenoid Peripheral Posts has the same indications for and intended use, material, sterilization, packaging, and bearing sizes as the previously cleared INHANCE Reverse Shoulder System, K212737. The difference between the subject and predicate device is that the subject glenoid has a modular peripheral post instead of a modular peripheral screw to aid in stability. Because of these similarities, the subject of this submission, the INHANCE Reverse Glenoid Peripheral Posts, is substantially equivalent to the predicate INHANCE Reverse Shoulder System, cleared in K212737 on April 21, 2022.

The subject INHANCE Reverse Glenoid Peripheral Posts has the same indications for and intended use, materials, fixation area, fixation options, and design intent as the previously cleared Catalyst OrthoScience R1 Reverse Shoulder System, K202611. Any noted differences do not raise different questions of safety or effectiveness.

Non-Clinical Testing:

The INHANCE™ Reverse Shoulder System with Peripheral Posts underwent non-clinical testing and analyses using well-established methods to evaluate the change and 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. The subject Peripheral Posts do not represent a new worst-case component within the construct as it relates to range of motion when compared to the compatible implants cleared in K212737 (INHANCE Reverse Shoulder System).

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. The materials and processes used in the manufacture of the Peripheral Posts and accessory instruments are identical to those used on implants and accessory instruments cleared in K212737 (INHANCE Reverse Shoulder System).

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 (INHANCE Anatomic Shoulder System) and K212737 (INHANCE Reverse Shoulder System).

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

The subject Peripheral Posts do not represent a new worst-case component within the construct as it relates to force, torque, heating, or image quality in the MR environment when compared to the compatible implants cleared in K212737 (INHANCE Reverse Shoulder System).

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.

The subject Peripheral Posts use the same material and sterile packaging as the predicate implants cleared in K212737 (INHANCE Reverse Shoulder System) and, therefore, do not raise different questions of safety and effectiveness as it relates to shelf-life.

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}.

The subject Peripheral Posts use the same material, manufacturing locations, and sterile packaging as the predicate implants cleared in K212737 (INHANCE Reverse Shoulder System) and, therefore, do not raise different questions of safety and effectiveness as it relates to device sterility.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the INHANCE™ Reverse Glenoid Peripheral Posts 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 is substantially equivalent to the predicate device.