July 21, 2023

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

Re: K231516
Trade/Device Name: INHANCE™ Shoulder System, Sterile Single Use Instrumentation
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, PHX, KWT, KWS, PAO, HSD
Dated: May 24, 2023
Received: May 25, 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 (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,

Thomas Mcnamara -S

Digitally signed by Thomas Mcnamara -S
Date: 2023.07.21 09:57:23 -04'00'

For: Farzana Sharmin, Ph.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)*
K231516

Device Name
INHANCE™ Shoulder System, Sterile Single Use Instrumentation

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 INHANCETM SHOULDER SYSTEM with the 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 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 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.

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510(k) Summary

Prepared: July 20, 2023

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

Contact:
Russ Parrott
Chief Technology Officer
Phone: 574.527.2864
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Proprietary Name: INHANCE™ Shoulder System, Sterile Single Use Instrumentation

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 semi-constrained cemented prosthesis; (21 CFR §888.3660); Class II

Shoulder joint metal/polymer non-constrained cemented prosthesis; (21 CFR §888.3650); Class II

Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis; (21 CFR §888.3690); Class II

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

Predicate Devices:
K202716 (Primary) - INHANCE Anatomic Shoulder System;
DePuy Ireland UC (formerly Ignite Anatomic Shoulder System; Ignite Orthopedics LLC)
K212737 – INHANCE Reverse Shoulder System; DePuy Ireland UC

Reference Devices:

K203108 – INHANCE (Ignite) Stemless Anatomic Shoulder System; DePuy Ireland UC
K212933 – INHANCE Hybrid Anatomic Glenoid; DePuy Ireland UC

Device Description:
The current submission adds single use instruments to the INHANCE Shoulder System. The single use instruments are packaged individually or in sterile kits. The implant components of the system are unchanged.

The INHANCE™ 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).

Indications for Use:
Anatomic Total Shoulder or Hemi-Shoulder

The INHANCE SHOULDER SYSTEM with the <u>humeral stemless anchor</u> 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 the 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 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 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:

The INHANCE Sterile Single Use Instruments are intended to be used during surgical procedures of the INHANCE Shoulder System in accordance with its Indications for Use. The INHANCE Sterile Single Use Instruments have the same indications for and intended use as the previously cleared instruments in the INHANCE Anatomic Shoulder System and Reverse Shoulder System, K202716 and K212737. The differences between the subject and predicate device is the materials used, how the devices are supplied (sterile vs non-sterile), and whether or not the devices are intended to be re-used/re-processed.

Substantial Equivalence:

The INHANCE Sterile Single Use Instruments are substantially equivalent to the predicate device in regards to their intended use and indications, material, design, sizes, and performance. The implant components of the subject device system are identical to those of the predicate device as they remain unchanged. Differences between the subject device system and the predicate device systems do not raise new types of safety and effectiveness questions.

Non-Clinical Testing:

The implant components of the INHANCE Shoulder System are identical to the implant components of the predicate device. This submission includes additional, single use instruments.

The INHANCE™ Sterile Single Use Instruments underwent non-clinical testing and analyses to support a determination of substantial equivalence to the predicate device. The following were completed:

Design Validation

Simulated use of the subject devices was conducted in cadavers and bone analogue materials to confirm that the devices properly prepare the surgical site for implants within the INHANCE Anatomic and Reverse Shoulder Systems. The devices functioned and performed as intended.

Biocompatibility Assessments

The contact classification for the subject devices is Instrument, Bone/Tissue with limited duration (<24 hours). 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.

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. 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™ Sterile Single Use Instruments to the predicate devices.

Conclusion:

A comparison of the subject and predicate devices, including comparison of the indications for 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.