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

December 2, 2022

Re: K223211
Trade/Device Name: INHANCETM Shoulder System - Humeral Stems and Stemless
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, PKC, PAO, HSD
Dated: October 14, 2022
Received: October 17, 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,

Victoria A. Lilling -S

Digitally signed by Victoria A. Lilling -S
Date: 2022.12.02 15:24:38 -05'00'

Victoria Lilling, M.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
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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)*

K223211

Device Name

INHANCE™ Shoulder System - Humeral Stems and Stemless Anchors

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 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 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: October 14, 2022

Submitter:
Ignite Orthopedics LLC
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Winona Lake, IN 46590

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

Proprietary Name: INHANCE™ Shoulder System – Humeral Stems and Stemless Anchors

Common Name: Anatomic and 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, Hemi-, Humeral, Metallic Uncemented, (21 CFR §888.3690); Class II

Prosthesis, Total Anatomic Shoulder, Uncemented Metaphyseal Humeral Stem With No Diaphyseal Incursion, Semi-Constrained (21 CFR §888.3660); Class II

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

	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (21 CFR §888.3690); Class II
Product Codes:	PHX, MBF, KWT, KWS, PKC, PAO, HSD
Predicate Device:	K212737 – (Primary) INHANCE Reverse Shoulder System, DePuy Ireland UC K202716 – INHANCE Anatomic Shoulder System; DePuy Ireland UC (formerly Ignite Anatomic Shoulder System; Ignite Orthopedics LLC) K203108 – INHANCE Stemless Anatomic Shoulder System; DePuy Ireland UC (formerly Ignite Stemless Anatomic Shoulder System; Ignite Orthopedics LLC)

Device Description:

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), peripheral posts (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 humeral head and 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 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 Shoulder System – Humeral Stems and Stemless Anchors has the same indications for use intended use, material, manufacturing method, sterilization, and packaging as the previously cleared devices in the INHANCE Anatomic Shoulder System (K202716), the INHANCE Stemless Anatomic Shoulder System (K203108), and the INHANCE Reverse Shoulder System (K212737).

The difference between the subject and predicate device is in the printing orientation and layer thickness in the additive manufacturing process of the stemmed humeral anchors. The finished form (geometry and biocompatibility) of the device is unaffected. Modifications to the additive manufacturing process do not result in greater risks of device fracture/failure. Because of these similarities, the subject of this submission, the INHANCE Shoulder System – Humeral Stems and Stemless Anchors, is substantially equivalent to the predicate INHANCE Anatomic Shoulder System (K202716), INHANCE Stemless Anatomic Shoulder System (K203108), and INHANCE Reverse Shoulder System (K212737).

Non-Clinical Testing:

The INHANCE™ Shoulder System Humeral Stems and Stemless Anchors were evaluated using well-established methods to demonstrate substantial equivalence to the predicate devices.

The following evaluations were completed:

Construct Fatigue Testing

Construct fatigue testing was performed on the subject devices per the methods described in ASTM F1378. The test methods and acceptance criteria were the same as utilized for the predicate devices. The acceptance criteria were met, demonstrating substantial equivalence of the subject and predicate devices.

Range of Motion (RoM) Evaluation

The geometry of the subject and predicate devices are identical. Therefore, the subject devices do not represent a new worst-case for range of motion when compared to the predicate devices.

Construct Loosening and Disassociation

The geometry of the subject and predicate devices are identical. Therefore, the subject devices do not represent a new worst-case for construct loosening and disassociation when compared to the predicate devices.

Biocompatibility Assessments

The raw materials and contact materials used in the manufacture of the subject Humeral Stems and Stemless Anchors are identical to those used on implants cleared in the predicate device submissions. Therefore, the subject devices do not represent a new worst-case for biocompatibility when compared to the predicate devices.

Porous Structure Characterization

The porous structure used for the subject device is identical to the porous structure that was applied to the predicate devices. Therefore, further characterization was not required.

MRI Compatibility

The geometry and magnetism of the materials of the subject and predicate devices are identical. Therefore, the subject devices do not represent a new worst-case for MRI compatibility when compared to the predicate devices.

Shelf Life Evaluation

The subject devices use the same material and sterile packaging as the predicate devices. Therefore, the subject devices do not represent a new worst-case for shelf life when compared to the predicate devices.

Sterilization Validation

The subject devices use the same material, manufacturing locations, and sterile packaging as the predicate devices. Therefore, the subject devices do not represent a new worst-case for sterility when compared to the predicate devices.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the INHANCE™ Shoulder System Humeral Stems and Stemless Anchors to the predicate devices.

Conclusion:

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