March 11, 2026

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% Yayoi Fujimaki
Regulatory Affairs Technical Manager
DePuy Orthopaedics, Inc.
700 Orthopaedic Dr.,
Warsaw, Indiana 46582

Re: K253624
Trade/Device Name: INHANCE™ Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, KWT, MBF, PAO
Dated: February 12, 2026
Received: February 12, 2026

Dear Yayoi Fujimaki:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

FARZANA SHARMIN -S

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253624

Device Name
INHANCE™ Reverse Shoulder System

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)
• Revision of previously failed shoulder joint replacement

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 Post 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) #: K253624

510(k) Summary

Prepared on: 2026-03-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	DePuy Ireland UC
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Applicant Contact	Ms. Yayoi Fujimaki
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Correspondent Address	700 Orthopaedic Drive N/A Warsaw IN 46582 United States
Correspondent Contact Telephone	617 837 1918
Correspondent Contact	Ms. Yayoi Fujimaki
Correspondent Contact Email	yfujima1@its.jnj.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	INHANCE™ Reverse Shoulder System
Common Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Classification Name	Shoulder Prosthesis, Reverse Configuration
Regulation Number	888.3660
Product Code(s)	PHX, KWS, KWT, MBF, PAO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K212737	INHANCE™ Reverse Shoulder System	PHX
K192855	DELTA XTEND™ Reverse Shoulder System	PHX
K122698	AEQUALIS™ ASCEND™ FLEX Reverse Shoulder System	PHX

Device Description Summary

21 CFR 807.92(a)(4)

The INHANCE Reverse Total Shoulder System 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), a baseplate (titanium alloy), peripheral screws (titanium alloy), a baseplate augment (titanium alloy), and either a central screw (titanium alloy) or a central post (titanium alloy). The purpose of this submission is to add alternate angle humeral liners to the INHANCE reverse shoulder system. The subject device is manufactured from a Cross-linked, VE UHMWPE. Size options include diameter 32mm, 36mm and 40mm with thickness +0mm or +4mm. Standard and Retentive options are available.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Anatomic Total Shoulder or Hemi-Shoulder

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• 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.

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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.
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Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The overall design of the subject humeral liner is similar to the predicate INHANCE humeral liner (K212737) with the key differentiation being the addition of a 10-degree inclination to the subject humeral liner. While the small technological difference is identified, the humeral neck-shaft angles of the INHANCE Reverse Shoulder System fall within the legally marketed predicate reverse shoulder system devices. The intended use and principles of operation remain unchanged. Device material, sterilization method, and sterile packaging barrier are the same as the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical studies and analyses were performed. Applicable technical standards, guidance or well-established test methods were referenced for the evaluations.

- Construct fatigue
- Wear characteristics
- Geometric Comparison
- Range of Motion (ASTM F1378)
- MR (magnetic resonance) safety (ASTM F2052, ASTM F2119, ASTM F2182, ASTM F2213)
- Biocompatibility (ISO 10993-1)
- Sterilization validation (ISO 11137-1, ISO 11137-2)
- Packaging integrity and stability (ISO 11607-1, ISO 11607-2)

Clinical Study was not applicable.

Based on the comparison of the technological characteristics and the engineering analyses, it can be concluded that the subject device is substantially equivalent to the predicate. The difference in the technological characteristics did not raise any different questions in safety and performance.