December 23, 2024

Depuy Ireland UC
% Sanjay Shah
Regulatory Affairs NPD
Depuy Orthopaedics, Inc.
700 Orthopaedic Dr.
Warsaw, Indiana 46582

Re: K243248
Trade/Device Name: Inhance Intact™
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PKC, PAO, MBF, KWT, KWS, HSD
Dated: October 4, 2024
Received: October 11, 2024

Dear Sanjay Shah:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2024.12.23 14:45:23 -05'00'

for: 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243248

Device Name

INHANCE INTACT™

Indications for Use *(Describe)*

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

Fixation Methods:
The humeral stemless anchor is intended for cementless use. The anatomic glenoid and anatomic hybrid glenoid are intended for cemented use only.

The INHANCE INTACT™ instruments are intended to be used during orthopedic surgery with INHANCE™ Anatomic Stemless Shoulder System. Cases and trays are intended to hold joint reconstruction instruments during the sterilization process and for storage.

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) #:

510(k) Summary

Prepared on: 2024-12-23

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Depuy Ireland UC
Applicant Address	Loughbeg Ringaskiddy Ringaskiddy Co. Cork Munster Ireland
Applicant Contact Telephone	(612) 812-6462
Applicant Contact	Mr. Sanjay Shah
Applicant Contact Email	sshah164@its.jnj.com
Correspondent Name	Depuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Dr. Warsaw IN 46582 United States
Correspondent Contact Telephone	(612) 812-6462
Correspondent Contact	Mr. Sanjay Shah
Correspondent Contact Email	sshah164@its.jnj.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	INHANCE INTACT™
Common Name	Prosthesis, Total Anatomic Shoulder, Uncemented Metaphyseal Humeral Stem With No Diaphyseal Incursion, Semi-Constrained
Classification Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulation Number	888.3660
Product Code(s)	PKC, PAO, MBF, KWT, KWS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K203108	Ignite Stemless Anatomic Shoulder System	PKC
K212933	INHANCE Hybrid Anatomic Glenoid Implant	MBF

Device Description Summary

21 CFR 807.92(a)(4)

The current submission adds INHANCE INTACT™ Instruments to the INHANCE Stemless Anatomic Shoulder System. The implant components of the system are unchanged. The INHANCE INTACT™ Instruments are designed to facilitate a subscapularis sparing total shoulder arthroplasty for the INHANCE™ Anatomic Stemless Shoulder System.

The INHANCETM SHOULDER SYSTEM with a humeral stemless anchor is intended for use in anatomic total shoulder replacement procedures.

The Anatomic Total Shoulder Prosthesis consists of individually packaged implants: a humeral stemless anchor (titanium alloy), an offset taper adapter (titanium alloy), a humeral head (cobalt- chromium) in combination with an anatomic glenoid (stainless steel x-ray marker pin embedded) or an anatomic hybrid glenoid featuring a metal central post (titanium alloy). All glenoid implants have a Cross-Linked, Vitamin E Ultra High Molecular Weight Polyethylene (Cross-Linked, VE UHMWPE) bearing surface.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Fixation Methods:
The humeral stemless anchor is intended for cementless use. The anatomic glenoid and anatomic hybrid glenoid are intended for cemented use only.

The INHANCE INTACT™ instruments are intended to be used during orthopedic surgery with INHANCE™ Anatomic Stemless Shoulder System. Cases and trays are intended to hold joint reconstruction instruments during the sterilization process and for storage.

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 INHANCE Stemless Anatomic Shoulder System with INHANCE INTACT instruments are substantially equivalent to the predicate device (K203108 and K212933) in regard to their intended use, indications for use, material, manufacturing process and performance. The implant components of the subject device system are identical to those of the predicate device as they remain unchanged. The INHANCE INTACT instruments have new design and specification compared to predicate devices instruments. Differences between the subject device system and the predicate device systems do not raise different types of safety and effectiveness questions.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

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

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

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.

Bench Testing:
Design equivalence, equivalence of use of the device, material rationale and biocompatibility evaluation demonstrate substantial equivalence.

Clinical testing was not required to demonstrate substantial equivalence.

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 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.