April 4, 2024

Depuy Ireland UC
Jennifer Hill
Regulatory Affairs Project Leader
Loughbeg, Ringaskiddy
County Cork, Ireland

Re: K240639
Trade/Device Name: PINNACLE™ Constrained Acetabular Liners
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip Joint Metal/Polymer Constrained Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWZ
Dated: March 6, 2024
Received: March 6, 2024

Dear Jennifer Hill:

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.

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,

Limin Sun -S

Limin Sun, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240639

Device Name

PINNACLETM Constrained Acetabular Liner

Indications for Use *(Describe)*

The PINNACLETM Constrained Acetabular Liner is indicated for use as a component of a total hip prosthesis in primary or revision patients at high risk of hip dislocation due to a history or prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability and for whom all other options of constrained acetabular components have been considered.

The PINNACLETM Constrained Acetabular Liner is indicated for use with the PINNACLETM Acetabular Cup in cementless application.

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

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork Ireland
Phone number	(+44) 7834974433
Fax number	N/A
Establishment Registration Number	3015516266
Name of contact person	Jennifer Hill
Date prepared	06th March 2024
Name of device	
Trade or proprietary name	PINNACLE™ Constrained Acetabular Liners
Common or usual name	Acetabular Cup Prosthesis
Classification name	**21 CFR 888.3310**: Hip joint metal/polymer constrained cemented or uncemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	Class II – 21 CFR 888.3310
Product Code(s)	**KWZ**: Prosthesis, Hip, Constrained, Cemented Or Uncemented, Metal/Polymer

Legally marketed device(s) to which equivalence is claimed	K043058/K052079/K071117 - PINNACLE™ Constrained Acetabular Liners
Reason for 510(k) submission	DePuy Ireland UC has compiled a Special 510(k) Premarket Notification to expand the labeling for the DePuy PINNACLE™ Constrained Acetabular Liners, to provide updated information regarding the MRI compatibility of the devices. A program of MRI Safety Evaluation testing has been carried out with full test data present and reviewed in the FDA cleared submission *'K231873 – DePuy Hip Portfolio MRI Bundled Traditional 510(k)'*. Appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients. At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices.
Device description	The PINNACLE™ Constrained Acetabular Liner is part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The liner is manufactured from ultra-high molecular weight polyethylene (UHMWPE), which locks into a porous coated, hemispherical outer shell component manufactured from titanium alloy (Ti-Al6-V4). The liner component articulates with a metal femoral head of an appropriate diameter.

	The PINNACLE™ Constrained Acetabular Liner mechanically constrains the femoral head within the inner diameters of the liner by providing greater than 180 degrees femoral head capture combined with a titanium constraining ring which fits over the opening diameter of the liner. The UHMWPE liner is held in the metal shell by means of a titanium locking ring. The PINNACLE™ Constrained Acetabular Liners are UHMWPE acetabular cup liners that are available in a lateralized neutral or lateralized face-changing orientation. The liners have inner diameters compatible with standard metal femoral heads sized 28, 32, and 36mm, as well as larger diameter unipolar, Self-Centering (bipolar) and Modular M femoral heads sized 40 and 44mm. The outer diameters (OD) are geometrically the same as other Pinnacle Acetabular Liners, in a 48mm-76mm size range offering.
Intended use of the device	Total hip arthroplasty is intended to replace the damaged hip joint articulation in patients at a high risk of hip dislocation, where there is evidence of sufficient sound bone to seat and support the components.
Indications for use	The PINNACLE™ Constrained Acetabular Liner is indicated for use as a component of a total hip prosthesis in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability and for whom all other options to constrained acetabular components have been considered. The PINNACLE™ Constrained Acetabular Liner is indicated for use with the PINNACLE™ Acetabular Cup in cementless application.
Substantial Equivalence	DePuy Ireland UC has compiled a Special 510(k) Premarket Notification to expand the labeling for the DePuy PINNACLE™ Constrained Acetabular Liners, to provide updated information regarding the MRI compatibility of the devices. A program of MRI Safety Evaluation testing has been carried out with full test data present and reviewed in the FDA cleared submission *'K231873 – DePuy Hip Portfolio MRI Bundled Traditional 510(k)'*. Appropriate amends have been made to the product labels and Instructions for Use (IFU), along with the provision of new MR Safety Cards for patients.

	At the same time as making these labeling updates in relation to MRI compatibility, DePuy will take the opportunity to standardize language and symbols used across its legacy devices for consistency, including the use of new internationally recognized symbols with corresponding updated symbols glossaries. Additionally, in order to harmonize with International and EU labeling requirements, the labeling of subject devices which are sold Internationally will be further updated to also include a new Implant Card, Implant Card Guide, and Implant Card Label. These are not US requirements and can be discarded by the end user. The labeling will also be updated to include a material code with corresponding material descriptions. There is no change to the indications, intended use, safety, fit, form or technological characteristics of the devices. Non-clinical testing is provided to support the conditional safety of the PINNACLE™ Constrained Acetabular Liners in the MR environment, including assessment of; • Magnetically Induced Displacement Force (ASTM F2052-21) • Magnetically Induced Displacement Torque (ASTM F2213-17) • Radio Frequency (RF) Heating (ASTM F2182-19) • Image Artifacts (ASTM F2119-07) The non-clinical performance data demonstrate that the Subject Devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.