April 28, 2021

Depuy Ireland UC
Floriane Heinrich
Regulatory Affairs Project Leader
Loughbeg Ringaskiddy
Co. Cork,
Ireland

Re: K203532
Trade/Device Name: BI-MENTUM™ ALTRX® Dual Mobility Liner
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH
Dated: April 1, 2021
Received: April 2, 2021

Dear Floriane Heinrich:

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,

Vesa Vuniqi
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K203532

Device Name

BI-MENTUM™ ALTRX® Dual Mobility Liner

Indications for Use *(Describe)*

BI-MENTUM™ ALTRX® Dual Mobility System is indicated for total hip replacement in the following conditions:
- Osteoarthritis
- Femoral neck fracture
- Dislocation risk
- Osteonecrosis of the femoral head
- Revision procedures where other treatments or devices have failed and if bone reconstruction so permits

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

(As required by 21 CFR 807.92)

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg Ringaskiddy Co. Cork, Ireland
Phone number	+334 72792851
Establishment Registration Number	3015516266
Name of contact person	Floriane Heinrich
Date prepared	November 30, 2020
Name of device	
Trade or proprietary name	BI-MENTUM™ ALTRX® Dual Mobility Liner
Common or usual name	Total hip prosthesis – Acetabular component
Classification name	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3353
Product Code(s)	LZO, MEH
Legally marketed device(s) to which equivalence is claimed	BI-MENTUM™ Dual Mobility System (K181744, cleared December 11, 2018) Reference device: PINNACLE® ALTRX® insert (K072963, cleared January 8, 2008 and K132959, cleared March 10, 2014)
Reason for 510(k) submission	Line extension – The subject device is dual mobility liner ALTRX® (ultra-high molecular weight polyethylene) manufactured from DePuy.
Device description	The BI-MENTUM™ ALTRX® Dual Mobility Liner is highly cross-linked ultra-high molecular weight polyethylene. The liner is mobile (free) in the metallic shell and retained on the prosthetic femoral head. The BI-MENTUM™ ALTRX® Dual Mobility Liner is compatible with all the stems listed on K181744 as well as all the BI-MENTUM™ cups cleared in K181744. The BI-MENTUM™ ALTRX® Dual Mobility Liner is also compatible with the PINNACLE® Dual Mobility Liner, cleared in K200854.
Intended use of the device	BI-MENTUM™ ALTRX® Dual Mobility Liners are designed to provide additional stability where there is an unstable joint and are for use in total hip

	arthroplasty that is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation or a previously implanted prosthetic hip joint in patients where there is evidence of sufficient sound bone to seat and support the components. The BI-MENTUM™ ALTRX® Dual Mobility Liners are intended for single use only.
Indications for use	**BI-MENTUM™ ALTRX® Dual Mobility Liner is indicated for total hip replacement, which includes:** - Osteoarthritis - Femoral neck fracture - Dislocation risk - Osteonecrosis of the femoral head - Revision procedures where other treatments or devices have failed are if bone reconstruction so permits

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE			
Characteristics	**Subject Device: BI-MENTUM™ ALTRX® Dual Mobility Liner**	**Predicate Device: SERF BI-MENTUM™ Dual Mobility System (K181744)**	**Reference Device: DePuy PINNACLE® ALTRX® Acetabular Liners (K072963, K132959)**
Intended Use	Total Hip Arthroplasty	Same	Same
Liner Material	UHMWPE, GUR 1020	UHMWPE, GUR 1050	UHMWPE, GUR 1020
Fixation	Uncemented	Same	Same
Dual Mobility	Yes	Yes	No
Dual Mobility Design	Monobloc dual articulation	Monobloc dual articulation	N/A
Compatible Acetabular Shell Diameters	41 – 69 mm	Same	44 – 76 mm
Internal Diameter of Dual Mobility Liner	22.2 mm, 28 mm	Same	28, 32, 36, 40, 44 and 48 mm
Sterile Method	Gas Plasma	Gamma	Gas Plasma
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}
Packaging	Double PETG blister with Tyvek peel lid	Vacuum-packed in bags and sealed in blister packaging	Double PETG blister with Tyvek peel lid

Shelf Life	5 years	Same	Same

The subject BI-MENTUM™ ALTRX® Dual Mobility Liner has the same intended use and fixation as the predicate BI-MENTUM™ Dual Mobility System (K181744). The subject device is intended for total hip arthroplasty; is a dual mobility construct and is available in the same size range as the predicate device. The subject BI-MENTUM™ ALTRX® Dual Mobility Liner has the same intended use and the same material (UHMWPE GUR 1020) as the reference device DePuy PINNACLE® ALTRX® Acetabular Liners (K072963, K132959).

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The following tests were performed on the BI-MENTUM™ ALTRX® Dual Mobility Liner to demonstrate substantial equivalence of safety and efficacy with the predicate devices:

- Verification of product compatibility
- Standard walking wear testing (per ISO 14242-2)
- Stem-Liner Range of Motion
- Head assembly and retention force (per ASTM F1820-13)
- Impingement testing (per ASTM F2582-20) after accelerated aging (per ASTM F2003-02)
- Post impingement testing lever out testing (per ASTM F1820-13)
- The proposed devices also meet the requirement of bacterial endotoxin testing

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

No clinical tests were conducted to demonstrate substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The subject BI-MENTUM™ ALTRX® Dual Mobility Liner is substantially equivalent to the predicate BI-MENTUM™ Dual Mobility System.