November 8, 2024

Waldemar Link GmbH & Co. KG
% Luisa Moncada
Senior Regulatory Affairs Specialist
LinkBio Corp
69 King Street
Dover, New Jersey 07801

Re: K241636
Trade/Device Name: MobileLink Acetabular Cup System - Line Extension (Multiple)
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, MEH
Dated: October 11, 2024
Received: October 11, 2024

Dear Luisa Moncada:

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,

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)*

K241636

Device Name

MobileLink Acetabular Cup System - Line Extension (Multiple)

Indications for Use *(Describe)*

The MobileLink Acetabular Cup System is indicated for patients with mobility-limiting diseases, fractures, or defects of the hip joint or proximal femur which cannot be treated by conservative or osteosynthetic procedures.

Indications:
1) Primary and secondary osteoarthritis
2) Rheumatoid arthritis
3) Correction of functional deformities
4) Avascular necrosis
5) Femoral neck fractures
6) Revision after implant loosening dependent on bone mass and quality

The MobileLink Dual Mobility Insert is additionally indicated for:
7) Dislocation risks

Additional indications specific to the TrabecuLink Augments:
Primary or revision surgery for hip replacement as a prosthetic alternative to structural allograft in cases of segmental acetabular deficiencies.

The MobileLink Acetabular Shells are intended for cementless fixation. The TrabecuLink Augments are intended for cementless fixation to the bone and for cemented fixation to the mating shell.

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

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Date Prepared: November 8, 2024

Trade Name: MobileLink Acetabular Cup System – Line Extension (Multiple)

Common Name: Total hip replacement system

Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. 21 CFR §888.3358, product code LPH, LZO, and MEH

Classification and Panel: Class II, Orthopedic / 87

Predicate Devices:

Subect Device Components	Predicate Devices	510(k) Number
MobileLink X-LINKed Inserts	1. MobileLink Acetabular Cup System, Polyethylene liners in neutral, offset, 10° and 20° inclinations *[Primary Predicate]* 2. DePuy Pinnacle AltrX Acetabular Cup Liner DePuy Orthopedics, Inc.	K182321 K062148
MobileLink TrabecuLink Augments	1. Trabecular Metal Acetabular Augments Zimmer, Inc. 2. Restoration Acetabular Wedge Augments Howmedica Osteonics Corp. (Stryker)	K061067, K042871, K102019
Bone Screws	1. MobileLink Acetabular Cup System Ø 6.5mm System Bone screws 2. Trilogy or Trabecular Metal Acetabular Cup Ø 4.5mm Screws (Zimmer)	K192559 K021891, K934765

Reason for Submission New Device System Components

Device Description: The MobileLink Acetabular Cup System is a versatile cup system, designed to provide several options for surgeons and patients within one system. This 510k adds several system components to the MobileLink Acetabular Cup System previously cleared in K182321, K192559, K200607, and K222066.

X-LINKed Inserts: The X-LINKed Inserts are manufactured from highly crosslinked polyethylene material. The inserts are available in the same sizes and designs as the previously cleared E-Dur inserts (K182321). The design variants include a neutral variant with or without offset, a shouldered variant with or without

offset and 10° and 20° inclining variants with an offset. The inserts are fixed using a clamping system consisting of a combination of snap mechanism and conical clamping. Notches (tabs/recesses) at the rim further contribute to the rotational stability of the PE inserts.

TrabecuLink Augments: The TrabecuLink Metal Acetabular Augments are wedge-shaped components that conform to the shape of the acetabular shell. They are additively manufactured Ti6Al4V alloy per ISO 5832-3 (chemistry and mechanical properties) and feature a porous structure (TrabecuLink) on the bone interfacing surface. They mate with the same MobileLink (TrabecuLink) Shells as previously cleared in K182321 and K222066 and they can be used with the same 6.5mm diameter bone screws cleared in K192559, or with new smaller diameter (4.5mm) bone screws introduced in this submission.

Bone Screws: The MobileLink Bone Screws are Ø 4.5mm in lengths from 15 – 60mm (by 5mm increments). They feature the same head size/design as the previously cleared Ø 6.5mm screws and are made of the same wrought Ti6Al4V alloy per ISO 5832-3 and ASTM F136 as the previously cleared Ø 6.5mm screws.

Intended Use:

General indications:
The MobileLink Acetabular Cup System is indicated for patients with mobility-limiting diseases, fractures or defects of the hip joint or proximal femur which cannot be treated by conservative or osteosynthetic procedures.

Indications:

1) Primary and secondary osteoarthritis
2) Rheumatoid arthritis
3) Correction of functional deformities
4) Avascular necrosis
5) Femoral neck fractures
6) Revision after implant loosening dependent on bone mass and quality

The MobileLink Dual Mobility Insert is additionally indicated for:

7) Dislocation risks

Additional indications specific to the TrabecuLink Augments:

8) Primary or revision surgery for hip replacement as a prosthetic alternative to structural allograft in cases of segmental acetabular deficiencies.

The MobileLink Acetabular Shells are intended for cementless fixation.
The TrabecuLink Augments are intended for cementless fixation to the bone and for cemented fixation to the mating shell.

Comparison to Predicate Device:

The subject MobileLink X-LINKed Inserts are substantially equivalent to the previously cleared MobileLink E-Dur inserts (K182321) in terms of design, intended use, manufacturing method, sterilization, and packaging. The only difference is that the subject devices are made from a highly crosslinked poly that doesn't contain Vitamin E. The crosslinked material of the subject devices is similar to the material of the AltrX device.

The subject TrabecuLink Augments serve the same purpose and are of similar wedge-shaped design as the cited predicate devices. The feature of the additive manufactured porous surface is equivalent to the predicate Zimmer augments (K042871, K061067) and Stryker augments (K102019). The subject TrabecuLink Augments differ from the predicate device Trabecular Metal Acetabular Augments from Zimmer (K042871, K061067) in that the predicate device appear to be porous

throughout with no solid core while the subject devices feature a solid core with porous structure at the surface.

The subject and predicate bone screws all provide supplemental screw fixation for acetabular shells used with or without acetabular augments. There are no differences in intended use.

The subject and predicate bone screws are all manufactured from Ti6Al4V alloy. The predicate Ø 6.5mm bone screws of the MobileLink Acetabular Cup System have already been cleared via K192559 and are available in lengths from 15mm – 80mm. The subject and predicate Zimmer Bone Screws are both available in Ø 4.5mm, and lengths of 15mm – 60mm. Any minor differences in technological features do not raise new questions of safety or effectiveness.

Performance Testing:

Non-clinical performance testing and analysis were provided, including:

- Acetabular construct disassembly testing (Push-out, lever-out, torque out for the acetabular modular connections)
- Range of Motion evaluation (comparison to predicate)
- Wear (rationale based on material properties and design similarity)
- Impingement testing
- Shell/Augment construct fatigue testing
- Bone screw testing per ASTM F543
- Characterization of the TrabecuLink porous surface
- Biocompatibility evaluation

The results of non-clinical performance testing demonstrate that the device is as safe and effective as the predicate device, and therefore Substantially Equivalent.

Clinical Testing:

Clinical performance testing was not required to demonstrate the substantial equivalence of this device.

Conclusion:

The subject MobileLink X-LINKed Inserts and TrabecuLink Augments are substantially equivalent to the predicate devices identified in this premarket notification.