May 16, 2025

Waldemar Link GmbH & Co.KG
% Terry Powell
V.P. Regulatory Affairs
LinkBio Corp. (U.S. Distributor/Initial Importer)
69 King Street
Dover, New Jersey 07801

Re: K243927
Trade/Device Name: MobileLink Acetabular Cup System - inhouse coatings
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 14, 2025
Received: April 14, 2025

Dear Terry Powell:

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,

RYAN TROMBETTA -S

For: 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.

510(k) Number *(if known)*
K243927

Device Name
MobileLink Acetabular Cup System - inhouse coatings

Indications for Use *(Describe)*
General Indications:
The MobileLink Acetabular Cup System is indicated for mobility-limiting diseases, fractures or defects of the hip joint or proximal femur which cannot be treated by conservative or osteosynthetic procedures.

Indications:
- Primary and secondary osteoarthritis
- Rheumatoid arthritis
- Correction of functional deformities
- Avascular necrosis
- Femoral neck fractures
- Revision after implant loosening dependent on bone mass and quality

Dual Mobility Insert (in addition to the indications and general indications):
- Dislocation risk

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.

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.

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 (K243927)

510(k) Submitter:
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Date Prepared: May 16, 2025

Trade Name: MobileLink Acetabular Cup System – inhouse coatings

Common Name: Total hip replacement system

Classification Name: 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, product code LZO/MEH

Classification and Panel: Class II, Orthopedic / 87

Predicate Devices: See table below.

Subject Device Components	**Predicate Devices**	**510(k) Number**
MobileLink Acetabular Cup System, PlasmaLink and TiCaP Shells	MobileLink Acetabular Cup System *[Primary Predicate]*	K241636
	Reference Devices	**510(k) Number**
	LINK BiMobile Dual Mobility System MobileLink Acetabular Cup System SP-CL Hip Stem and LCU Hip System	K171273 K182321 K213770

Reason for Submission

Addition of alternate coating vendor for the MobileLink PlasmaLink and TiCaP Shells of the MobileLink Acetabular Cup System: Change in PlasmaLink and TiCaP coatings supplier to allow an inhouse process (in addition to the current external supplier).

Device Description:

The MobileLink Acetabular Cup System is a versatile cup system, designed to provide several options for surgeons and patients within one system.

MobileLink PlasmaLink and TiCaP Shells: The MobileLink System consists of press-fit metal shells made of a Ti6Al4V alloy. The system offers two designs, a cluster hole shell, with closing screws and a polar screw, and a multi hole shell. Both shells are available with two different coatings, either titanium plasma sprayed (TPS) coating (brand name: PlasmaLink) or a double coating consisting of titanium plasma spray coating plus calcium phosphate (CaP) coating (brand name: TiCaP). The MobileLink PlasmaLink and TiCaP Shells are compatible with polyethylene liners (K182321, K241636), acetabular bone screws (K192559), Dual Mobility Inserts (K200607) with BiMobile Dual Mobility Liners (K171273,

K190535), Shell/Insert Adapters ("Face Changers", K200607), and TrabecuLink Augments (K241636).

Intended Use:

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

Indications:

- Primary and secondary osteoarthritis
- Rheumatoid arthritis
- Correction of functional deformities
- Avascular necrosis
- Femoral neck fractures
- Revision after implant loosening dependent on bone mass and quality

Dual Mobility Insert (in addition to the indications and general indications):

- Dislocation risk

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.

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.

Comparison to Predicate Device:

The subject MobileLink Shells with PlasmaLink coating or TiCaP coating produced inhouse are similar to the previously cleared MobileLink shells with PlasmaLink or TiCaP coating, and differ only with respect to the coating vendor used (change in PlasmaLink and TiCaP coatings supplier to allow an inhouse process in addition to the current external supplier).

Performance Testing:

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

- Characterization of the TPS and TiCaP inhouse coatings
- 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 Shells with PlasmaLink or TiCaP inhouse coatings are substantially equivalent to the predicate devices identified in this premarket notification.