July 6, 2026

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

Re: K261009
Trade/Device Name: MobileLink Acetabular Cup System - 40mm ID Inserts (various)
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, OQG, LPH
Dated: June 8, 2026
Received: June 9, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261009

Please provide the device trade name(s).

MobileLink Acetabular Cup System – 40mm ID Inserts (various)

Please provide your Indications for Use below.

General Indications:
– 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 Surgery
Dual Mobility Insert (in addition to the indications and general indications):
– Dislocation risk
The MobileLink Acetabular Shells are intended for uncemented fixation
The TrabecuLink Augments are intended for uncemented 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

510(k) Submitter:
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Facility Registration: 300317426

Contact Person:
LinkBio Corp.
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E-Mail: l.moncada@linkbio.com

Date Prepared: 2026-07-02

Trade Name: MobileLink Acetabular Cup System – 40mm ID Inserts (various)

Common Name: Total hip replacement system

Classification Name:
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.; 21 CFR §888.3353, product code LZO

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.; 21 CFR §888.3353, product code MEH

Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. 21 CFR §888.3358, product code OQG

Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. 21 CFR §888.3358, product code LPH

Classification and Panel: Class II, Orthopedic / 87

Predicate Devices:

Subject Device Components	Predicate Devices	510(k) Number
40mm Inserts	1. MobileLink Actabular Cup System *[Primary Predicate]*	K182321
	2. MobileLink Actabular Cup System – Line Extension *[Additional Predicate]*	K241636

Subject Device Components	Reference Devices	510(k) Number
40mm Inserts	1. Zimmer Biomet G7 Acetabular System [*Reference*]	K140669

Reason for Submission New acetabular inserts that can accomodate 40mm heads in the larger acetabular shell OD sizes.

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 acetabular insert components to the MobileLink Acetabular Cup System previously cleared in K182321, K192559, K200607, K222066, and K241636.

40mm Inserts: The 40mm Inserts are manufactured from highly crosslinked with Vitamin E (E-Dur) and highly crosslinked without Vitamin E (X-LINKed)

polyethylene material. The designs include standard and 5mm shoulder variants which currently exist in the MobileLink Acetabular Cup System cleared in K182321 and K241636. The 40mm inserts are available only for the larger acetabular shell sizes (OD sizes 54-80mm). 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.

Intended Use:

General Indications:

- 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 Surgery

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

- Dislocation risk

The MobileLink Acetabular Shells are intended for uncemented fixation

The TrabecuLink Augments are intended for uncemented 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 40mm Inserts are substantially equivalent to the previously cleared MobileLink E-Dur and X-LINKed inserts (K182321 and K241636) in terms of design, intended use, manufacturing method, sterilization, and packaging, and have an inner diameter similar to the reference device.

Performance Testing:

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

- Evaluation of acetabular construct disassembly testing (Push-out, lever-out, torque out for the acetabular modular connections) conducted per ASTM F1820
- Range of Motion evaluation
- Wear testing under standard conditions per ISO 14242 and ASTM F1877
- Evaluation of impingement testing conducted per F2582
- Biocompatibility evaluation

The results of non-clinical performance testing demonstrate Substantial Equivalence to the predicate.

Clinical Testing:

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

Conclusion:

The subject MobileLink 40mm Inserts are substantially equivalent to the predicate devices identified in this premarket notification.