April 14, 2023

Waldemar Link GmbH & Co KG
℅ Terry Powell
Regulatory Affairs
LinkBio Corp.
59 King Street
Dover, New Jersey 07801

Re: K222066
Trade/Device Name: LINK MobileLink Acetabular Cup System
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, OQG
Dated: March 20, 2023
Received: March 21, 2023

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 (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,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K222066

Device Name
LINK MobileLink Acetabular Cup System

Indications for Use *(Describe)*
General indications:
Mobility-limiting diseases, fractures or defects 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

The MobileLink Acetabular Shells are intended for cementless fixation.

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

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Date Prepared: April 14, 2023

Trade Name: LINK MobileLink Acetabular Cup System

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, OQG

Classification and Panel: Class II, Orthopedic / 87

Predicate Devices:

Subect Device Components	Predicate Devices	510(k) Number
TrabecuLink Shells	1. MobileLink Acetabular Cup System Pro Codes: LPH, LZO, MEH, OQG Waldemar Link GmbH & Co KG *[Primary Predicate]*	K182321, K192559, K200607
	2. G7 OsseoTi Acetabular Shell Pro Codes: LPH, JDI, KWZ, LZO, OQG, OQH, OQI, PBI Biomet, Inc. (Zimmer Biomet)	K140669

Reason for Submission New Device System Components – TrabecuLink Shells

Device Description: This 510k adds MobileLink TrabecuLink Acetabular Shells to the MobileLink Acetabular Cup System previously cleared in K182321, K192559, K200607.

These shells are additively manufactured from Ti6Al4V alloy per ISO 5832-3 and feature a porous structure (TrabecuLink) on the bone interfacing surface for biologic fixation. The shells come in cluster-hole and in multi-hole patterns.

They

mate with the same UHMWPE liners (in conventional PE and highly-crosslinked vitamin E PE) as previously cleared in K182321, and with the same Dual Mobility Inserts and Shell/Insert Adapters previously cleared in K200607. They can be used with the same bone screws cleared in K192559.

Intended Use:

General indications:
The MobileLink Acetabular Cup System is indicated for patients with mobility-limiting diseases, fractures or defects 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

The MobileLink Acetabular Shells are intended for cementless fixation.

Comparison to Predicate Device:

The subject MobileLink TrabecuLink Acetabular Shells differ from the predicate MobileLink Acetabular Shells (K182321) in that the subject shells are additive manufactured and feature a 3-D porous surface (TrabecuLink) that is integrated with the shell substrate during the additive manufacturing process. This feature (additively manufactured shell with integrated porous surface) is equivalent to the predicate Zimmer/Biomet G7 Acetabular Cup System with OsseoTi Shells (K140669).

The subject MobileLink TrabecuLink Acetabular Shells are similar to the predicate MobileLink Acetabular Shells (K182321) in that they are made of Ti6Al4V alloy, and come in the same sizes and design variants (cluster hole or multi-hole), have the same interior geometry and mate with all of the same previously cleared MobileLink polyethylene inserts, Dual Mobility CoCr Inserts, Adapters (face changers) and bone screws.

Performance Testing:

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

- Acetabular deformation testing
- Acetabular fatigue testing
- Assessment of disassembly (Push-out, lever-out, torque out for all acetabular modular connections in MobileLink system)
- Assessment of range of motion
- Characterization of the TrabecuLink porous surface
- Biocompatibility evaluation
- Particle analysis

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 TrabecuLink Acetabular Shells are substantially equivalent to the predicate devices identified in this premarket notification.