May 28, 2021

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

Re: K200607
Trade/Device Name: MobileLink® Acetabular Cup System – Dual Mobility Liners, and Shell/Insert Adapters
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: OQG, LPH
Dated: February 1, 2021
Received: February 1, 2021

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,

for

William Jung, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200607

Device Name
LINK MobileLink(R) Acetabular Cup System – Dual Mobility Liners, and Shell/Insert Adapters

Indications for Use *(Describe)*
General indications:
The MobileLink(R) 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(R) Dual Mobility Insert is additionally indicated for:

7) Dislocation risks

The MobileLink(R) 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

510(k) Submitter:
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Date Prepared: May 27, 2021

Trade Name: LINK MobileLink® Acetabular Cup System - Dual Mobility Liners, and Shell/ Insert Adapters

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 OQG, LPH

Classification and Panel: Class II, Orthopedic / 87

Predicate Devices:

Subect Device Components	Predicate Devices	510(k) Number
Dual Mobility Inserts	1. Modular Dual Mobility (MDM) Liner Pro Codes: LZO, MEH Stryker Orthopaedics (Howmedica Osteonics) *[Primary Predicate]*	K103233
	2. G7 Dual Mobility System Pro Codes: LPH, KWY, LZO, OQG Biomet Inc. (Zimmer Biomet)	K150522
	3. BiMobile Dual Mobility System Pro Codes: MEH, LZO Waldemar Link GmbH & Co KG	K190535
Shell/Insert Adapters	1. MobileLink®Acetabular Cup System, Polyethylene liners in neutral, offset, 10° and 20° inclinations *[Primary Predicate]*	K182321
	2. Modular Dual Mobility (MDM) Liner Pro Codes: LZO, MEH Stryker Orthopaedics (Howmedica Osteonics)	K103233

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.

Dual Mobility Inserts: The Dual Mobility Inserts are manufactured from CoCrMo alloy. They assemble by taper lock to any MobileLink® Acetabular Shell (either the PlasmaLink or TiCaP versions cleared in K182321) and mate with polyethylene Dual Mobility Liners (from the BiMobile System cleared in K171273 and K190535.

Shell/Insert Adapters ("face changers"): These are optional components that can be used as an interface between the MobileLink® Acetabular metal shells (either the PlasmaLink or TiCaP versions cleared in K182321) and the neutral and shouldered polyethylene inserts to adjust the center of rotation and anteversion angles. They are manufactured from Ti6Al4V alloy, and come in various designs: neutral, offset, offset with 10° inclination, and offset with 20° inclination. The neutral version assembles to the mating shell by taper lock only, while the other versions assemble by taper lock plus an assembly screw.

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 and predicate Dual Mobility Inserts are each modular CoCr inserts that fit within titanium alloy acetabular shells by means of a taper connection to allow a dual mobility construct wherein a femoral head articulates within the poly liner, and a poly liner articulates within the Dual Mobility Insert assembled within the acetabular shell.

The subject Shell/Insert Adapters are used within a modular acetabular construct to allow the surgeon to adjust the center of rotation and to adjust the anteversion angles by 10° or 20° (depending on design). This is the same purpose as the predicate MobileLink polyethylene liners (K182321) which also allow the surgeon to adjust the center of rotation and to adjust the anteversion angles by 10° or 20° (depending on design). The Shell/Insert Adaptors introduce another modular junction (between the shell and the polyethylene liner), but this technological difference raises no new questions of safety or effectiveness, and

established non-clinical tests of the modular assembly are sufficient to demonstrate substantial equivalence.

Performance Testing:

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

- Acetabular construct disassembly testing (Push-out, lever-out, torque out for all acetabular modular connections)
- Fretting/Corrosion testing
- Impingement testing
- Range of Motion analysis according to ISO 21535
- 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® Acetabular Cup System is substantially equivalent to the predicate devices identified in this premarket notification.