Waldemar Link GmbH & Co. KG
Karen Sonnenberger
Regulatory Affairs Specialist
Oststrabe 4-10
Norderstedt, 22844 De

May 24, 2019

Re: K182321
Trade/Device Name: MobileLink Acetabular Cup System
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: April 25, 2019
Received: April 26, 2019

Dear Karen Sonnenberger:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 CAPT Raquel Peat, PhD, MPH, USPHS
Director
Office of Health Technology 6
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)*
K182321

Device Name
MobileLink® Acetabular Cup System

Indications for Use *(Describe)*
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 qualityThe shells are

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

510(k) Submitter:	Waldemar Link GmbH & Co. KG Barkhausenweg 10 22339 Hamburg, Germany Phone: +49-40-539950 Facility Registration: 3003386935 (Oststraße 4-10) Facility Registration: 3007118403 (Harckesheyde 95)
Contact Person:	Waldemar Link GmbH & Co. KG Dr. Karen Sonnenberger *(Regulatory Affairs)* Oststraße 4-10 22844 Norderstedt, Germany Phone: +49-40 53995-530 Fax: +49-40 53995-174 E-Mail: k.sonnenberger@linkhh.de
Date Prepared:	May 22, 2019
Trade Name:	MobileLink® Acetabular Cup System
Common Name:	Acetabular Shells
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:	G7 Acetabular System, K121874, K140669, K142882 (Biomet) Trinity Acetabular System, K093472, K110087, K123705, K111481 (Corin)
Reference Devices:	EXp highly crosslinked Vitamin E UHMWPE acetabular shell liners, K094035 (Stelkast) Delta TT Actabular Cups, K112898 (Lima Corp.) PlasmaCup with Vitalene Poly, K122873 (Aesculap) HGPII, K840643, K901364 (Zimmer) Omnifit, K912654, K911728 (Osteonics Corp.) PCA, K920831 (Howmedica) Opti-Fix, K864857 (Richards Medical) Tri-Loc, 942966, K943302,K862702 (DePuy) Integrity, K935206, K940486 (Kirschner Medical Corp.) Logical Cup System Acetabular Bone Screws, K121297 (Signature Orthopaedics) LINK® BiMobile™ Dual Mobility System, K171273 (LINK Gmbh & Co KG)

Pipeline Total Hip System, K112802 (Pipeline Orthopaedics)

Reason for Submission	New Device
Device Description:	The MobileLink® Acetabular Cup System is a versatile cup system, designed to provide several options for surgeons and patients within one system. The cup 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 plasma sprayed coating (PlasmaLink®) or a double coating consisting of plasma spray plus calcium phosphate coating (TiCaP®). All shells are implanted cementless. The acetabular inserts are manufactured from conventional UHMWPE or Vitamin E highly crosslinked UHMWPE (E-Dur®). The inserts are available in six designs, neutral, offset, shouldered, offset/shouldered, 10° and 20° inclination. This premarket notification does not include the femoral components. The MobileLink® Acetabular Cup System is compatible with previously cleared femoral heads (K161840, K953653) and hip stems and neck segments (K161840, K151008, K142187, K953653) of Waldemar Link GmbH & Co. KG.
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
Comparison to Predicate Device:	The subject device is substantially equivalent to the G7 Acetabular System from Biomet (K121874, K140669, K142882) in terms of intended use, design, range of sizes and materials used. The subject device is substantially equivalent to the Trinity™ System (K093472, K110087, K123705) in terms of intended use, design, range of sizes and materials including coating. Features comparable to the predicate devices include the same indication, dimensions, materials, shelf life, surgical implantation technique and intended use.
Performance Testing:	Non-clinical performance testing and analysis were provided, including bench testing, UHMWPE and coating characterization, endotoxin testing, and biocompatibility testing (for the E-Dur® UHMWPE). <u>Bench testing included</u>: - Disassembly testing (Axial push-out, offset pullout, and torsional tests according to ASTM F1820) for the liner/shell assembly. - Wear test according to ISO 14242-1 and particle analysis per ISO 17853 and ASTM F1877 – wear rates compared to Stelkast Exp highly crosslinked Vitamin E UHMWPE acetabular shell liners - Wear testing under adverse conditions and particle analysis - Range of Motion according to ISO 21535

- Endotoxin testing
- Impingement testing per ASTM F2582

Coating characterization: The coatings were evaluated per "*Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarked Surveillance Requirements*" and "*510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants*" Testing included microstructural analysis, mechanical testing and metallurgical analysis.

PE characterization included: The PE materials were characterized according to FDA Guidance, "Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices," and included material characterization, HXL characterization and aging study, and biocompatibility testing and evaluation per ISO 10993.

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 device MobileLink® Acetabular Cup System are substantially equivalent to the predicate devices identified in this premarket notification.