December 21, 2019

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

Re: K192559
Trade/Device Name: Acetabular Bone Screws (for 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: September 17, 2019
Received: September 17, 2019

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,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K192559

Device Name
MobileLink® Acetabular Cup System with Acetabular Bone Screws

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 quality

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) Submitter:	Waldemar Link GmbH & Co. KG Barkhausenweg 10 22339 Hamburg, Germany Phone: +49-40-539950 FEI Number: 3003386935 (Oststraße 4-10)
Contact Person:	Waldemar Link GmbH & Co. KG Dr. Karen Sonnenberger *(Regulatory Affairs)* Oststraße 4-10 22844 Norderstedt, Germany Establishment Registration Number: 3004371426 Phone: +49-40 53995-517 Fax: +49-40 53995-174 E-Mail: k.sonnenberger@linkhh.de
Date Prepared:	December 19, 2019
Trade Name:	Acetabular Bone Screws (MobileLink® Acetabular Cup System)
Common Name:	Bone Screws
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:	Waldemar Link GmbH & Co KG, MobileLink Acetabular Shells (K182321) Signature Orthopedics 6.5mm bone screws (K121297) [Primary]
Reason for Submission	Add accessory bone screws to predicate acetabular cup system
Device Description:	The subject devices are 6.5mm diameter acetabular bone screws in various lengths manufactured from Ti6Al4V alloy. They are accessories to the predicate MobileLink® Acetabular Cup System (K182321).
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 acetabular bone screws are intended for optional use with the parent MobileLink Acetabular Shell bodies (K182321) in cases where the surgeon chooses supplemental bone screw fixation. They do not change the indications for use of the parent device systems. The bone screws are manufactured from the same Ti6Al4V alloy per ISO 5832-3 and ASTM F136 used for manufacture of the parent MobileLink Acetabular Shell bodies (K182321).

The subject and predicate bone screws (K121297) provide supplemental screw fixation for acetabular shells, are manufactured from Ti6Al4V alloy, are available in Ø 6.5mm and various lengths. Minor differences in technological features do not raise new questions of safety or effectiveness. Bench testing demonstrated equivalent performance.

Performance Testing:

Non-clinical testing and analysis included:

- Bone screw testing according to ASTM F543
- Endotoxin testing
- 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 bone screws for the MobileLink® Acetabular Cup System are substantially equivalent to the predicate devices identified in this premarket notification.