June 3, 2022

Waldemar Link GmbH & Co. KG
Stefanie Fuchs
Regulatory Affairs
Oststraße 4-10,
Norderstedt, DEU 22844

Re: K211567
Trade/Device Name: BiMobile Instruments (for use with Dual Mobility 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
Dated: May 21, 2021
Received: May 21, 2021

Dear Stefanie Fuchs:

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, Ph.D.
Acting 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211567

Device Name
BiMobile Instruments (for use with BiMobile Dual Mobility System)

Indications for Use *(Describe)*
The BiMobile Dual Mobility System is indicated for patients with mobility-limiting diseases, fractures or defects of hip joint or proximal femur, which cannot be treated by conservative or osteosynthetic procedures.

The BiMobile Dual Mobility System is indicated for the following conditions:
- Primary and secondary coxarthrosis
- Rheumatoid arthritis
- Correction of functional deformities
- Avascular Necrosis
- Femoral neck fractures
- Revision after implant loosening dependent on bone mass and quality
- Dislocation risks

The device is intended for cemented and cementless use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(k) Submitter:	Waldemar Link GmbH & Co. KG Barkhausenweg 10 22339 Hamburg, Germany Phone: +49-40-539950 Facility Registration #:3003386935
Contact Person:	Waldemar Link GmbH & Co. KG Stefanie Fuchs *(Regulatory Affairs)* Oststraße 4-10 Norderstedt, GERMANY 22844 Phone: +49-40 53995-530 Fax: +49-40 53995-174 E-Mail: st.fuchs@linkhh.de
Date Prepared:	June 2, 2022
Trade Name:	BiMobile Instruments (for BiMobile Dual Mobility System)
Common Name:	Acetabular Cup
Classification Name:	Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous; 21 CFR §888.3353, product code LZO Prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate; 21 CFR §888.3353, product code MEH
Predicate Devices:	LINK BiMobile Dual Mobility System, K171273, cleared January 19, 2018 LINK BiMobile Dual Mobility System – E-Dur Inserts, K190535, cleared August 6, 2019
Device Description:	The BiMobile instruments are considered a line extension to the instrument system cleared in 510(k) K171273 and K190535 with the BiMobile Dual Mobility System. Like the original instruments, the additional BiMobile instruments are manual orthopedic surgical reusable instruments offered to aid the implantation of the BiMobile Dual Mobility System (K171273 and K190535). The BiMobile Instruments incorporate design changes for simplicity of use. The modifications do not significantly alter the surgical workflow or technique, the intended use, or involve any change in technology.
Indications for Use:	The BiMobile Dual Mobility System is indicated for patients with mobility-limiting diseases, fractures or defects of hip joint or proximal femur, which cannot be treated by conservative or osteosynthetic procedures.

The BiMobile Dual Mobility System is indicated for the following conditions:

- Primary and secondary coxarthrosis
- Rheumatoid arthritis
- Correction of functional deformities
- Avascular Necrosis
- Femoral neck fractures
- Revision after implant loosening dependent on bone mass and quality
- Dislocation risks

The device is intended for cemented and cementless use.

Technological Characteristics and Substantial Equivalence

The modified Class II accessory instruments within the BiMobile Instrument system that are the subjects of this 510(k) have the same intended use, operating principle, basic device designs and purposes, and materials as the unmodified instruments. The modified impactor handles with the corresponding impactor expanders create the same impaction of the shells, but feature minor design changes for simplicity and ease of use. The substantial equivalence of the modified to the original instruments was supported by non-clinical testing and evaluations including:

- Simulated transport testing
- Biocompatibility assessment
- Interface analysis, functional testing, biolab evaluation, application risk analysis
- Durability testing
- Validation of reprocessing and sterilization instructions

Conclusion: The subject BiMobile Instruments that are subject of this 510(k) (Class II accessory instruments) are substantially equivalent to the predicate instruments identified in this premarket notification.