August 6, 2019

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

Re: K190535
Trade/Device Name: BiMobile Dual Mobility System - E-Dur Inserts
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: July 8, 2019
Received: July 11, 2019

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,

Vesa Vuniqi
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190535

Device Name
BiMobile Dual Mobility System - E-Dur Inserts

Indications for Use *(Describe)*
The BiMobile Dual Mobility System is indicated for patients with mobility-limiting diseases, fractures or defects of the 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 osteoarthritis
- 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.

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510(k) Summary

510(k) Submitter:

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Date Prepared:

July 07, 2019

Trade Name:

BiMobile Dual Mobility System – E-Dur Inserts

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

Classification and Panel:

Class II, Orthopedic / 87

Predicate Devices:

LINK BiMobile Dual Mobility System, K171273, cleared January 19, 2018

Trinity Dual Mobility System with ECiMa Liners by Corin, K170359, cleared October 31, 2017

EXp Acetabular Shell Liner by Stelkast, Inc., K094035, cleared March 24, 2011

MobileLink Acetabular Cup System, K182321, cleared May 24, 2019

Device Description:

The BiMobile cup system is a dual mobility acetabular implant system. The system is consisting of wrought cobalt chromium molybdenum alloy (CoCrMo acc. to ISO 5832-12)

metal shells with a highly polished inner surface, which are available in three different outer surface modifications. There is the cemented version with a glass blasted surface of concentric grooves, and two cementless versions where a pressfit generating macrostructure is covered by either a PlasmaLink (titanium plasma spray acc. to ISO 5832-2/ASTM F1580) or TiCaP (titanium plasma spray and calcium phosphate acc. to ISO 5832-2/ASTM F1580 and F1609) coating. For each size, from 42 to 70, a dedicated liner made of Ultra-high-molecular-weight polyethylene (conventional UHMWPE acc. to ISO 5834-2/ASTM F648) is available. These can be combined with ceramic or CoCr alloy femoral heads of sizes 22 mm (for Size 42-46) and 28 mm (for size 48-70).
The purpose of this submission is to add acetabular liners in Vitamin E highly crosslinked UHMWPE (E-Dur) acc. to ASTM F2695, ASTM F2565 to the BiMobile Dual Mobility System.

This premarket notification does not include the femoral components. The BiMobile Dual Mobility System is compatible with previously cleared femoral heads (K171273, K161840, K953653, K931571, and K920756), femoral stems and neck segments (K183141, K161840, K151008, K142187, and K953653,) of Waldemar Link GmbH & Co. KG.

Indications for Use:

The BiMobile Dual Mobility System is indicated for patients with mobility-limiting diseases, fractures or defects of the 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:

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
7) Dislocation risks

The device is intended for cemented and cementless use.

Comparison to Predicate Device:

The additional components of the BiMobile Dual Mobility System are similar to the predicate devices in terms of intended use and indications, materials, sizes, designs and performance.

Based on these similarities, the additional components of the BiMobile Dual Mobility System are believed to be substantially equivalent to the predicate device.

Performance Testing:

Non-Clinical Performance and Conclusions:
The following material characterization, biocompatibility testing/analysis, wear analyses, mechanical testing were performed to demonstrate that the BiMobile E-Dur® Inserts perform as intended and are substantially equivalent to the identified devices:

- Material Characterization
- Biocompatibility Testing and Analysis
- Axial Disassembly Testing
- Lever-out Testing
- Standard and Adverse Wear Anaylses including Particles Analyses
- Range of Motion Analysis

The results of non-clinical performance testing demonstrate that the device is as safe, as effective, and substantially equivalent to the predicate devices.

Clinical Testing:

Clinical performance Testing was not required to demonstrate the substantial equivalence of this device.

Conclusion:

The subject device BiMobile E-Dur inserts is substantially equivalent to the predicate devices identified in this premarket notification.