Waldemar Link GmbH & Co. KG
Henrik Kroh
Regulatory Affairs
Barkhausenweg 10
22339 Hamburg, Germany

January 19, 2018

Re: K171273
Trade/Device Name: LINK® BiMobile™ 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: MEH, LZO
Dated: December 20, 2017
Received: December 22, 2017

Dear Mr. Kroh:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171273

Device Name
LINK® BiMobile™ Dual Mobility System

Indications for Use *(Describe)*
The LINK® BiMobile™ Dual Mobility System is indicated for patients with mobility-limiting diseases, fractures or defects which cannot be treated by conservative or osteosynthetic procedures.
The LINK® BiMobile™ Dual Mobility System is indicated for the following conditions:

- Primary and secondary coxarthrosis
- Osteoarthritis
- Necrosis of the femoral head
- Femoral neck fractures
- Revision after implant loosening
- Acetabular dysplasia

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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510(k) Summary

510(k) Submitter:

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Date Prepared:

January 19th, 2018

Trade Name:

LINK® 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

Classification and Panel:

Class II, Orthopedic / 87

Predicate Devices:

Restoration™ ADM System by Howmedica, K072020, cleared October 18, 2007

Trinity Acetabular System by Corin, K093472, cleared November 23, 2010

NOVAE® Dual Mobility Acetabular Cup by SERF, K111572, cleared August 29, 2011

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).

This premarket notification does not include the femoral components. The LINK® BiMobile™ Dual Mobility System is compatible with the FDA cleared LINK® femoral stems of the SP-CL® / LCU® (K161840); and the Lubinus SPII® (K953653) hip systems, with the MP® Reconstruction Prosthesis (K142187) and MEGASYSTEM-C® (K151008) neck segments and with the femoral heads made of cobalt-chromium and ceramic.

Indications for Use:

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

1) Primary and secondary coxarthrosis
2) Osteoarthritis
3) Necrosis of the femoral head
4) Femoral neck fractures
5) Revision after implant loosening
6) Acetabular dysplasia

The device is intended for cemented and cementless use.

Comparison to Predicate Device:

The LINK® BiMobile™ Dual Mobility System is substantially equivalent to ADM® Mobile Bearing Hip System (K072020).
Features comparable to the predicate devices include the same indications, dimensions, materials, packaging, sterilization, surgical implantation technique and intended use.

Performance Data:

Non-Clinical Performance and Conclusions:
Non-clinical performance testing and analysis were provided, including bench testing, coating characterization and

endotoxin testing. Bench testing included: Wear test per ISO 14242-1 and -2; Particles Analyses per ISO 17853 and ASTM F1877; Liner Press-in testing; Lever-out testing, Axial Disassembly testing and Range of Motion analyses of the LINK® BiMobile™ Dual Mobility System.

The coating was evaluated per FDA Guidance Documents entitled "*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"*.

Coating characterization included: Microstructural analysis; Mechanical testing and Metallurgical 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 Performance and Conclusions:
There was no clinical performance testing required for this device.

Conclusion:

The subject device LINK® BiMobile™ Dual Mobility System with a PlasmaLink® or TiCaP® coating is substantially equivalent to the predicate devices identified in this premarket notification.