Waldemar Link GmbH & Co. KG
Andre Malotki
Official Correspondent
Oststraße 4-10
Norderstedt, 22844 De

February 8, 2019

Re: K183141
Trade/Device Name: LINK MP Monoblock Hip Prosthesis
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
Dated: November 13, 2018
Received: November 13, 2018

Dear Andre Malotki:

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,

Daniel S. Ramsey -S
2019.02.08 16:39:00 -05'00'

FOR 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)*

K183141

Device Name
LINK® MP® Monoblock Hip Prosthesis

Indications for Use *(Describe)*

The LINK® MP® Monoblock 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 LINK® MP® Monoblock is indicated for the following conditions:
- Revision of loosened femoral prosthesis components involving extensive bone resorption of the proximal femur and widening of the medullary cavity or marked thinning of proximal femoral cortical bone the fixation of a new standard prosthesis is not possible
- Revision of loosened femoral prosthesis components by peri-/subprosthetic fracture

The device is intended for 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.

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:

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"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."

SECTION 5: 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 André von Malotki *(Regulatory Affairs)* Oststraße 4-10 22844 Norderstedt, Germany Phone: +49-40 53995-530 Fax: +49-40 53995-174 E-Mail: a.vonmalotki@linkhh.de
Date Prepared:	November 8th, 2018
Trade Name:	*LINK*® MP® Monoblock Hip Prosthesis
Common Name:	Hip Revision Prosthesis
Classification Name:	21 CFR §888.3353, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Product Code	LZO
Classification and Panel:	Class II, Orthopedic / 87
Predicate Devices:	Wagner SL Revision Stem by Zimmer Biomet Holding, Inc., K973837, cleared January 6, 1998
Reference Device:	*LINK*® MP® Reconstruction Prostheses by Waldemar Link GmbH & Co. KG, K142187, cleared November 6, 2014 *LINK*® SP-CL® Hip System PoroLink® (Microporous) And HX® (CaP) Coated & *LINK*® LCU® Hip System PoroLink® (Microporous) And HX® (CaP) Coated by Waldemar Link GmbH & Co. KG, K161840, cleared March 16, 2017
Device Description:	The *LINK*® MP® Monoblock Hip Prosthesis is a straight hip prosthesis stem. The hip prosthesis is made of Titanium Aluminum Vanadium alloy (Ti-6Al-4V). The prosthesis stems are available in a range of sizes, lengths, CCD angles and offsets. Additional features include a tapered stem with a microporous glass-blasted surface. The *LINK*® MP® Monoblock Hip Prosthesis is designed to be used in conjunction with femoral heads that are manufactured from Cobalt Chromium Molybdenum casting alloy (CoCrMo) or ceramic

(BIOLOX® forte and BIOLOX® delta) via 12/14 morse taper (K161840). In total joint use, the femoral head articulates against *LINK*® BiMobile Cup System (K171273). The *LINK*® MP® Monoblock Hip Prosthesis provides cementless fixation to the bone.

Indications for Use:

The *LINK*® MP® Monoblock Hip Prosthesis 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 *LINK*® MP® Monoblock Hip Prosthesis is indicated for the following conditions:

- Revision of loosened femoral prosthesis components involving extensive bone resorption of the proximal femur and widening of the medullary cavity or marked thinning of proximal femoral cortical bone the fixation of a new standard prosthesis is not possible
- Revision of loosened femoral prosthesis components by peri-/subprosthetic fracture

The device is intended for cementless use.

Performance Data:

Non-Clinical Performance and Conclusions:
Non-clinical performance testing and analysis were provided, including bench testing. Specifically, the following tests were performed:

- Femoral stem fatigue
- Femoral neck segment fatigue
- Fretting corrosion testing
- 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 device.

Clinical Performance and Conclusions:
There was no clinical performance testing required for this device.

Conclusion:

The subject device *LINK*® MP® Monoblock Hip Prosthesis is substantially equivalent to the predicate devices identified in this premarket notification.