DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 17, 2017

Waldemar Link GmbH & Co. KG
Mr. André Von Malotki
Regulatory Affairs Manager
Oststraße 4-10
Norderstedt, Germany 22844

Re: K161840
Trade/Device Name: LINK® SP-CL® Hip System PoroLink® (microporous) and HX® (CaP) coated & LINK® LCU® Hip System PoroLink® (microporous) and HX® (CaP) coated
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: February 16, 2017
Received: February 16, 2017

Dear Mr. André Von Malotki:

This letter corrects our substantially equivalent letter of March 16, 2017.

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Lori A. Wiggins -S

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)*
K161840

Device Name
LINK® SP-CL® Hip System PoroLink® (microporous) and HX® (CaP) coated & LINK® LCU® Hip System PoroLink® (microporous) and HX® (CaP) coated

Indications for Use *(Describe)*

The LINK® SP-CL® and LCU® Hip System PoroLink® (microporous) and HX® (CaP) coated is indicated for patients with mobility-limiting hip diseases, fractures or defects which cannot be treated by conservative or osteosynthetic procedures.
The hip system is indicated for the following conditions:

- Primary and secondary coxarthrosis
- Osteoarthritis
- Necrosis of the femoral head
- Femoral neck fractures

The stems are indicated for cementless use only.

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:

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 #:3004371426 (Oststraße 4-10)

Contact Person:

Waldemar Link GmbH & Co. KG
André von Malotki *(Regulatory Affairs)*
Oststraße 4-10
Norderstedt, GERMANY 22844
Phone: +49-40 53995-448
Fax: +49-40 53995-174
E-Mail: a.vonmalotki@linkhh.de

Date Prepared:

March 10th, 2017

Trade Name:

LINK® SP-CL® Hip System PoroLink® (microporous) and HX® (CaP) coated

&

LINK® LCU® Hip System PoroLink® (microporous) and HX® (CaP) coated

Common Name:

Hip Prosthesis

Classification Name:

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; 21 CFR §888.3353, product code LZO, MEH

Classification and Panel:

Class II, Orthopedic / 87

Predicate Devices:

Corail AMT™ Hip Prosthesis by DePuy Orthopaedics, #K123991 cleared September 16, 2013; #K070554 cleared September 11, 2007; #K042992 cleared February 11, 2005

LINK® Contour Ribbed Hip Prosthesis, #K854465 cleared February 2, 1986

Device Description:

The *LINK*® SP-CL® and LCU® Systems include a straight stem (LCU® Hip Prosthesis) and an anatomically curved stem (SP-CL® Hip Prosthesis). Both stems are comprised of titanium alloy (Ti6A14V, ISO 5832-3, ASTM F136) available with corundum blasted PoroLink® (microporous) surface or HX® (calcium phosphate) (ASTM F1609) coated. The stems are available in a range of sizes, lengths, and offsets. The stems connect to femoral heads that are manufactured from Cobalt Chromium Molybdenum casting alloy (CoCrMo) or ceramic (BIOLOX® *forte* and BIOLOX® *delta*) via 12/14 Morse taper. In total joint use, the femoral head articulates against Signature Orthopedics' Origin crosslinked acetabular liners (#K121297) fixed in a cementless shell. Femoral heads part of this submission (BIOLOX® *forte* / *delta* head and *LINK*® Prosthesis Head B) are not intended for hemi-arthroplasty use. Both the LCU® and SP-CL® stems are intended for cementless use to replace the hip joint.

Indications for Use:

The *LINK*® SP-CL® and LCU® Hip System PoroLink® (microporous) and HX® (CaP) coated is indicated for patients with mobility-limiting hip diseases, fractures or defects which cannot be treated by conservative or osteosynthetic procedures. The hip system is indicated for the following conditions:

- Primary and secondary coxarthrosis
- Osteoarthritis
- Necrosis of the femoral head
- Femoral neck fractures

The stems are indicated for cementless use only.

Comparison to Predicate Device:

Consistent with FDA's guidance document, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (July 28, 2014) (510(k) Guidance Document), the *LINK*® SP-CL® and LCU® Hip Systems are substantially equivalent to DePuy Orthopaedics' Corail AMT Hip Prosthesis (#K123991, #K070554, #K042992) and the *LINK*® Contour Ribbed Hip Prosthesis (#K854465). The *LINK*® SP-CL® and LCU® Hip Systems have the same intended use and the same or similar indications, technological characteristics, and principles of operation as the predicate devices.

Performance Data:

Non-Clinical Performance and Conclusions:

Non-Clinical performance testing was conducted with consideration to "*Guidance for Industry and FDA Staff, Non-Clinical Information for Femoral Stem Prosthesis, September 17, 2007"*.

Non-clinical performance testing included: femoral stem fatigue tests per ISO 7206-4 and ISO 7206-8; femoral neck segment fatigue tests per ISO 7206-6; ASTM F2068; Modular Connections, Fretting Corrosion Testing per ASTM F1875-98; Range of Motion analysis of the *LINK*® SP-CL® and LCU® Hip Systems and Component Testing of ceramic heads.

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:

There was no clinical performance testing required for this device.

Cleaning, Sterilization and Routine Endotoxin Testing:

Sterilization and cleaning studies validate the procedures used, per the applicable standards of AAMI ST 77:2006, AAMI ST79, ISO 17665-1, ISO 11138-3, AAMI TIR 12:2010, and AAMI TIR 30.

Routine Endotoxin Testing is performed according to AAMI ST 72.

Conclusion:

The *LINK*® LCU® and SP-CL® Systems have the same intended use and the same or similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the *LINK*® LCU® and SP-CL® Systems and its predicate device do not raise any new issues of safety or effectiveness.

The subject devices *LINK*® SP-CL® and LCU® Hip System PoroLink® (microporous) and HX® (CaP) coated are substantially equivalent to the predicate device identified in this premarket notification.