September 13, 2022

Waldemar Link GmbH & Co. KG
℅ Pia Müller
Regulatory Affairs Manager
Waldemar Link GmbH & Co. KG
Oststraße 4-10
Norderstedt, Germany 22844

Re: K213770
Trade/Device Name: SP-CL Hip Stem and LCU Hip 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: August 18, 2022
Received: August 18, 2022

Dear Pia Müller:

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.
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)*
K213770

Device Name
SP-CL Hip Stem and LCU Hip System

Indications for Use *(Describe)*

The SP-CL Hip Stem and LCU Hip System are indicated for patients with mobility-limiting hip diseases, fractures or defects which cannot be treated by conservative or osteosynthetic procedures.

The hip systems are 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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 Pia Müller *(Regulatory Affairs Manager)* Oststraße 4-10 Norderstedt, Germany 22844 Phone: +49-40 53995-841 Fax: +49-40 53995-174 E-Mail: p.mueller@linkhh.de
Date Prepared:	August 17th, 2022
Trade Name:	SP-CL Hip Stem and LCU Hip System
Common Name:	Hip Prosthesis
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:	Waldemar Link; LINK SP-CL Hip System PoroLink (microporous) and HX (CaP) coated & LINK LCU Hip System PoroLink (microporous) and HX (CaP) coated, K161840

Device Description:

The submission includes a straight stem, LCU Hip Sytem, and an anatomically curved stem, SP-CL Hip Stem. Both stems are comprised of titanium alloy (Ti6A14V acc. to ISO 5832-3, ASTM F136) available with HX (CaP) (ASTM F1609) coating. The stems are available in a range of sizes, lengths, and offsets. In total hip replacement, the SP-CL Hip Stem and LCU Hip System are combined with a corresponding prosthesis head and the acetabular implant components manufactured by Waldemar Link.

The change that is subject of this 510(k) is to add calcium phosphate coating (CaP) done by Waldemar Link inhouse to the above listed systems. The devices are already commercially available with CaP coating applied by an external vendor.

There is no change to the fundamental scientific technology of the referenced hip systems with the modifications in this 510(k) submission. This includes no changes to materials, design, sterilization, packaging, or method of manufactured. All components are sterile and for single use only.

Indications for Use:

The SP-CL Hip Stem and LCU Hip System are indicated for patients with mobility-limiting hip diseases, fractures or defects which cannot be treated by conservative or osteosynthetic procedures.

The hip systems are 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 the predicate:

The SP-CL Hip Stem and LCU Hip System with HX (CaP) inhouse coating are substantially equivalent to LINK SP-CL and LINK LCU Hip System PoroLink (microporous) and HX (CaP) coated (K161840).

The only change of the hip systems is the HX (CaP) coating applied inhouse, which is substantially equivalent to the HX (CaP) coating applied by the external vendor. Features comparable to the predicate devices include the same

indications, dimensions, materials, packaging, sterilization, surgical implantation technique and intended use.

Performance Testing:

Non-clinical performance testing and analysis were provided, including:

- Shear Testing (ASTM F1044-05)
- Tension Testing (ASTM F1147-05)
- Stereological Evaluation (ASTM F1854-15)
- Infrared Spectroscopy
- Dissolution/ Solubility Rate (ASTM F1926/F1926M-14)
- Elemental Analysis (ASTM F1609-08)
- Chemical Analysis (ASTM F1609-08)
- Shelf life
- Endotoxin testing

The results of non-clinical performance testing demonstrate that the device is suitable for its intended purpose and substantially equivalent to the predicates.

Clinical Testing:

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

Conclusion:

The subject devices SP-CL Hip Stem and LCU Hip System with HX (CaP) inhouse coating are substantially equivalent to the predicate device identified in this premarket notification.