April 11, 2022

Waldemar Link GmbH & Co. KG
Lydia Ditter
Regulatory Affairs
Ostsraße 4-10
Norderstedt, 22844
Germany

Re: K213675
Trade/Device Name: MP Reconstruction 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, JDI
Dated: April 8, 2022
Received: April 8, 2022

Dear Lydia Ditter:

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.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213675

Device Name
MP Reconstruction System

Indications for Use *(Describe)*
The MP Reconstruction System is intended for revision hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur. The MP Reconstruction System is indicated for the following conditions:
1. Revision arthroplasty due to juxta-articular bone defects.
2. 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.
3. Revision of loosened femoral prosthesis components by peri-/subprosthetic fracture.
4. Deformed proximal femur due to fractures or osteotomies.
5. Correction of bone deficiencies, e.g. due to tumors.
6. Large post-revision and post-trauma segmental bone defects.

The MP Reconstruction System is for cementless use. Only cemented labeled modular stems are indicated for cemented 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.

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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 Lydia Ditter *(Regulatory Affairs)* Oststraße 4-10 Norderstedt, GERMANY 22844 Phone: +49-40 53995-530 Fax: +49-40 53995-174 E-Mail: L.Ditter@linkhh.de
Date Prepared:	April 11, 2022
Trade Name:	MP Reconstruction System
Common Name:	Hip Revision Prosthesis
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR § 888.3353, product code LZO Hip joint metal/polymer semi-constrained cemented prosthesis; 21 CFR §888.3350, product code JDI
Classification and Panel:	Class II, Orthopedic / 87
Predicate Devices:	*LINK* MP Reconstruction Hip (K142187) – *Primary Predicate* *LINK* MEGASYSTEM-C (K151008)
Device Description:	This 510k adds Cemented Stems to the MP Reconstruction System. The MP Reconstruction System is a modular hip prosthesis system and consists of Prosthesis Heads, Stems, Neck Segments, Proximal Spacers, and Expansion Bolts. The modular components are interchangeable allowing for independent positioning. The Prosthesis Stems are available in a variety of diameters and lengths. Neck Segments are available in a variety of CCD angles and sizes. Proximal Spacers are available in two different heights and can be used

independently or combined to add leg length. Expansion Bolts are used to secure the Neck Segments and Proximal Spacers, when used, to the Prosthesis Stems.

The cementless prosthesis stems are tapered with a microporous surface, and include longitudinal fluting. The cemented prosthesis stems have a rounded triangular shape with an anatomic bow at the distal tip.

The MP Reconstruction Prosthesis Stems (cementless) and Neck Segments are produced of Titanium Aluminum Vanadium alloy (Ti-6Al-4V). Cemented Stems, Proximal Spacers and Expansion Bolts are made of Cobalt Chromium Molybdenum casting alloy (CoCrMo) materials.

Indications for Use:

The MP Reconstruction Prosthesis is intended for revision hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur. The MP Reconstruction Hip Prosthesis is indicated for the following conditions:

1) Revision arthroplasty due to juxta-articular bone defects.
2) 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.
3) Revision of loosened femoral prosthesis components by peri-/subprosthetic fracture.
4) Deformed proximal femur due to fractures or osteotomies.
5) Correction of bone deficiencies, e.g. due to tumors.
6) Large post-revision and post-trauma segmental bone defects.

The MP Reconstruction Prosthesis is for cementless use. Only cemented labeled modular stems are indicated for cemented use.

Comparison to Predicate Device:

The subject device has the same indications for use as the primary predicate, but includes the option of cemented stems. The subject device is made of materials identical to those used in the predicate and reference device systems. The subject device cemented prosthesis stems differ from the primary predicate cementless prosthesis stems in that the cemented stems are made of CoCrMo instead of Ti-6Al-4V and have a modified stem shaft design intended for use with bone

cement: They are cylindrical with 3 flattened sides, giving them a rounded triangular shape and a narrower distal tip with a slight bow.

The performance testing is sufficient to demonstrate that the subject and predicate devices are substantially equivalent with regard to design. Any difference between the subject and predicate device does not change the intended use or fundamental scientific technology.

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 and Guidance Document For Testing Non-Articulating,"Mechanically Locked", Modular Implant Components, May 1, 1995.*

Non-clinical performance testing included: femoral stem fatigue tests per ISO 7206-4.

The results of non-clinical performance testing demonstrated that the device is substantially equivalent to the predicate devices.

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

Conclusion:

The subject device cemented prosthesis stem of the MP Reconstruction System is substantially equivalent to the predicate devices identified in this premarket notification.