April 3, 2019

Waldemar Link GmbH & Co. KG
Andre von Malotki
Regulatory Affairs
Oststraße 4-10
22844 Norderstedt, Germany

Re: K182872
Trade/Device Name: LINK® GEMINI® SL® Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: March 1, 2019
Received: March 4, 2019

Dear Andre von 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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2019.04.03 23:55:12 -04'00'

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)*

K182872

Device Name

LINK® GEMINI® SL® Total Knee System

Indications for Use *(Describe)*

The LINK® GEMINI® SL® Total Knee System is indicated for patients suffering from disability due to:

- Degenerative, post-traumatic or rheumatoid arthritis;
- Avascular necrosis of the femoral condyle;
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
- Moderate valgus, varus or flexion deformities.

This device may also be indicated in the salvage of previously failed surgical attempts.
The device is indicated for cemented use. Only cementless labeled modular stems are indicated for uncemented 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: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:	December 28th, 2018
Trade Name:	*LINK*® GEMINI® SL® Total Knee System
Common Name:	Total Knee Prosthesis
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis; 21 CFR §888.3560, product code JWH
Classification and Panel:	Class II, Orthopedic / 87
Predicate Devices:	Foundation® Knee System, manufactured by DJO surgical, K923277, cleared 02/09/1993 Foundation® Posterior Stabilized Knee, manufactured by DJO surgical, K933539, cleared 11/08/1994 Foundation® Knee System with TiNbN Coating, manufactured by DJO surgical, K122239, cleared 04/11/2013
Device Description:	The *LINK*® GEMINI® SL® Total Knee System is a semi-constrained, patellofemorotibial, cemented knee prosthesis. It is intended to replace the three articular portions of the knee joint. The system compromises two different designs: “Cruciate Retaining (CR)” and “Posterior Stabilized (PS)”. The CR Version can be used if the posterior cruciate ligament (PCL) is intact. The PS version has a coupling mechanism, which prevents femoral ventral subluxation in flexion in the absence of the PCL. Both versions consist of similar components: a Cobalt Chromium femoral component a polyethylene patella and a Cobalt Chromium tibial baseplate with an Ultra High Molecular Weight Polyethylene (UHMWPE / non-crosslinked) insert. The fixation of the tibial baseplate can be extended due to modular stems. The femoral and

tibial components are made of CoCrMo and are available with PorEx® (K152431) surface modification.

Indications for Use:

The *LINK*® GEMINI® SL® Total Knee System is indicated for patients suffering from disability due to:

- Degenerative, post-traumatic or rheumatoid arthritis;
- Avascular necrosis of the femoral condyle;
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
- Moderate valgus, varus or flexion deformities.

This device may also be indicated in the salvage of previously failed surgical attempts.

The device is indicated for cemented use. Only cementless labeled modular stems are indicated for uncemented use.

Comparison to Predicate Device:

The *LINK*® GEMINI® SL® Total Knee System is substantially equivalent to the commercially available device Foundation® Knee System, in that both have same intended use and similar indications, design, materials, technological characteristics, and principles of operation. The minor technological differences between the *LINK*® GEMINI® SL® Total Knee System and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the *LINK*® GEMINI® SL® Total Knee System is as safe and effective as the Foundation® Knee System. Both devices are intended for cemented use and contain modular stems for cemented and cementless use. The femoral and tibial components are made of CoCrMo and are available with PorEx® (K152431) surface modification. The predicate device is available with the surface modification AmorCoat™ (K122239) produced by the same manufacturer DOT GmbH with same specifications.

Thus, the *LINK*® GEMINI® SL® Total Knee System is substantially equivalent.

Performance Data:

Non-Clinical Performance and Conclusions:

Non-Clinical performance testing was conducted with consideration to Draft Guidance For The Preparation of Premarket Notifications (510(k)s) for cemented, semi-constrained Total Knee Prostheses, April 1993, Guidance Document for Knee Joint patellofemorotibial and femorotibial metal/polymer porous-coated uncemented Prostheses, January 16, 2003

Non-clinical performance testing included: Tibial Baseplate Component fatigue test per ISO 14879 and ASTM F1800; Tibial Bearing Component wear test per ISO 14243-1 and -2; Particle Analyses test per ISO 17853 and ASTM F1877; Fretting Corrosion Testing per ASTM F1875-98; Tibial Post Fatigue Testing, Constraint

and Range of Motion Analyses.

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*® GEMINI® SL® Total Knee System is substantially equivalent to the predicate devices identified in this premarket notification.