May 13, 2021

Waldemar Link GmbH & Co. KG
℅ Terry Powell
Regulatory Affairs
LinkBio Corp.
69 King Street
Dover, New Jersey 07801

Re: K202924
Trade/Device Name: LinkSymphoKnee 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, HSX, HRY, OIY, KRO
Dated: April 5, 2021
Received: April 5, 2021

Dear Terry Powell:

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,

Ting Song, Ph.D., R.A.C.
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)*
K202924

Device Name
LinkSymphoKnee System

Indications for Use *(Describe)*
General:
The LinkSymphoKnee System is intended for primary and revision total knee replacement in skeletally mature patients with the following conditions.
This device is intended for cemented use only unless a cementless modular stem is indicated for use.

Indications:
- Primary degenerative arthritis / osteoarthritis
- Secondary arthritis resulting from rheumatoid arthritis
- Fracture

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 Stefanie Fuchs *(Regulatory Affairs)* Oststraße 4-10 Norderstedt, GERMANY 22844 Phone: +49-40 53995-530 Fax: +49-40 53995-174 E-Mail: st.fuchs@linkhh.de
Date Prepared:	May 12, 2021
Trade Name:	LinkSymphoKnee System
Common Name:	Knee Joint Replacement
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis, 21 CFR §888.3560, product code JWH Knee joint femorotibial metal/polymer non-constrained cemented prosthesis, 21 CFR §888.3520, product code HSX Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis, 21CFR §888.3530, product code HRY Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis, 21CFR §888.3560, product code OIY Knee joint femorotibial metal/polymer constrained cemented prosthesis, 21 CFR §888.3510, product code KRO
Classification and Panel:	Class II, Orthopedic / 87
Predicate Devices:	Primary Predicate: Waldemar Link LINK GEMINI SL Total Knee System: K182872 Additional Predicates: Smith & Nephew Legion Knee System: K072531, K041106, K043440; K953274; K951987

Waldemar Link Endo-Model Knee System: K143179
Waldemar Link Endo-Model Knee System with PorEx (TiNbN) coating: K152431

Device Description:

The LinkSymphoKnee System is available in multiple versions with different applications, characteristics, and materials.

The LinkSymphoKnee Cruciate Retaining (CR) Fixed Bearing (FB) (cemented) consists of a cemented femoral component for crucial retaining applications made from CoCrMo, a cemented tibial component for fixed bearing (FB) applications made from CoCrMo as monoblock or modular with a modular stem or a taper cap, and an articulating surface for crucial retaining and fixed bearing applications made from cPE or X-LINKed Vit-E PE (E-Dur).

The LinkSymphoKnee Posterior Stabilized (PS) Fixed Bearing (FB) (cemented) consists of a cemented femoral component for posterior stabilized applications made from CoCrMo, a cemented tibial component for fixed bearing applications made from CoCrMo as monoblock or modular with a modular stem or a taper cap, and an articulating surface for posterior stabilized and fixed bearing applications made from cPE or X-LINKed Vit-E PE (E-Dur).

Additonally, the tibial components can also be replaced by an All-Poly tibial component made from cPE.

The LinkSymphoKnee Posterior Stabilized Plus (PS+) Fixed Bearing (FB) (cemented) consists of a cemented femoral component for posterior stabilized applications made from CoCrMo, a cemented tibial component for fixed bearing applications made from CoCrMo as monoblock or modular with a modular stem or a taper cap, and an articulating surface for posterior stabilized plus and fixed bearing applications that provides more stability than the standard PS. The articulating surface PS+ provides a constraint from 0 to 3 degrees of varus/valgus and from 0 to 3 degrees of internal/external rotation and is made from cPE or X-LINKed Vit-E PE (E-Dur).

The LinkSymphoKnee Condylar Constrained (CCK) Fixed Bearing (FB) consists of a cemented femoral component for condylar constrained applications made from CoCrMo with a cemented modular stem made from CoCrMo or with a cementless modular stem made from TiAl6V4 (Tilastan), a cemented modular tibial component for fixed bearing applications made from CoCrMo with a cemented modular stem (CoCrMo with or without LINK PorEx (TiNbN) modification) or with a cementless modular stem made from TiAl6V4 (Tilastan), and an articulating surface for condylar constrained (CCK) and fixed bearing (FB) applications made from cPE or X-LINKed Vit-E PE (E-Dur).

The femoral components can be used with distal, posterior, and L-shaped femoral augments made from TiAl6V4 (Tilastan).

The modular tibial components can be used with tibial augments made from TiAl6V4 (Tilastan).

The femoral and tibial components are also available in LINK PorEx (TiNbN) coated version.

Additionally a 3-peg patella can be used with the LinkSymphoKnee System. It is made from cPE or X-LINKed Vit-E PE (E-Dur).

The LinkSymphoKnee System is compatible with previously cleared Tibial and Femoral Cones of Waldemar Link GmbH & Co. KG (K200113 and K201364).

Indications for Use:

General Indications:

The LinkSymphoKnee System is intended for primary and revision total knee replacement in skeletally mature patients with the following conditions.

This device is intended for cemented use only unless a cementless modular stem is indicated for use.

Indications:

- Primary degenerative arthritis / osteoarthritis
- Secondary arthritis resulting from rheumatoid arthritis
- Fracture

Comparison to the predicate: The LinkSymphoKnee System is substantially equivalent to the commercially available devices LINK Gemini SL Total Knee System and the Legion Total Knee System (Smith & Nephew) in that all have similar indications, design, materials and mechanicals safety. All devices are intended for cemented use only.

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

- Range of Motion analysis
- Wear analysis (ISO 14243-1 and -2)
- Particle analysis (ISO 17853 and ASTM F1877)
- Tibial baseplate component fatigue testing (ISO 14879 and ASTM F1800)
- Contact area/stress analysis
- Fretting / Corrosion (ASTM F1875)
- Disassembly / Constraint testing (ASTM F1223)
- Characterization of LINK PorEx (TiNbN) coating

	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 LinkSymphoKnee System is substantially equivalent to the predicate devices identified in this premarket notification.