March 21, 2023

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

Re: K230471
Trade/Device Name: LinkSymphoKnee - Fixed Bearing Ultracongruent (FB UC) Articulating Surface
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: February 21, 2023
Received: February 21, 2023

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 -S

Ting Song, 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.

Submission Number *(if known)*

K230471

Device Name

LinkSymphoKnee – Fixed Bearing Ultracongruent (FB UC) Articulating Surface

Indications for Use *(Describe)*

General Indications:
The LinkSymphoKnee 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.

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510(k) Summary

510(k) Submitter:

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Date Prepared:

February 24th, 2023

Trade Name:

LinkSymphoKnee – Fixed Bearing Ultracongruent (FB UC) Articulating Surface

Common Name:

Knee Joint Replacement

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:

Primary Predicate:
Waldemar Link LinkSymphoKnee: K202924

Reference Device:
Zimmer Biomet Persona UC Plateaus: K193223

Device Description:

The LinkSymphoKnee – Fixed Bearing Ultracongruent (FB UC) Articulating Surface is available in cPE and E-Dur. In cases of good joint stability, where the ligaments and capsule are intact the FB UC version is available. This configuration is provided for PCL retaining joint reconstruction or if the posterior cruciate ligament is sacrificed.

The Fixed Bearing Ultracongruent (FB UC) Articulating Surface is compatible with the already cleared LinkSymphoKnee (K202924). The LinkSymphoKnee is available in multiple versions with different applications, characteristics, and materials.

Indications for Use:

General Indications:

The LinkSymphoKnee 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 is substantially equivalent to the commercially available devices Persona Personalized Knee System [Zimmer Biomet] and the LinkSymphoKnee (Waldemar Link) 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)
- Particle analysis (ISO 17853 and ASTM F1877)
- Constraint analysis (ASTM F1223-20)
- Contact area/stress analysis

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