June 30, 2021

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

Re: K211768
Trade/Device Name: LINK Endo-Model Knee System, Femoral Segments (Augments), UHMWPE
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: June 8, 2021
Received: June 8, 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)*
K211768

Device Name
The LINK Endo-Model Knee System, Femoral Segments (Augments), UHMWPE

Indications for Use *(Describe)*
The LINK Endo-Model Knee System is indicated for patients with severe joint diseases with limitation of mobility due to degenerative, rheumatoid or post-traumatic arthrosis or arthritis. Joint fractures which disallow an osteosynthetic reconstruction. This device is intended for cemented use only unless a cementless modular stem is indicated for use.
The LINK Endo-Model® Rotating Hinge and Modular Rotating Hinge Knee System are indicated for the following conditions:
1) Bone necroses.
2) Bicondylar arthrosis by partly damaged collateral ligaments
3) Revision after primary total knee replacement.
4) Revision surgery after hinge knee or rotational knee joint.
5) Revision surgery by insufficient / inadequate bone mass.
6) Arthrosis of patella flange.
7) Valgus/Varus deformities <10°.
8) Valgus/Varus deformities 10-15°.
9) Valgus/Varus deformities 15-20°.
The LINK Endo-Model Non-Rotating Hinge and Modular Non-Rotating Hinge Knee System are indicated for the following conditions:
1) Bone necroses.
2) Bicondylar arthrosis by completely damaged ligaments and muscular instability.
3) Revision after primary total knee replacement.
4) Revision surgery after hinge knee or rotational knee joint.
5) Revision surgery by insufficient / inadequate bone mass.
6) Arthrosis of patella flange.
7) Valgus/Varus deformities <10°.
8) Valgus/Varus deformities 10-15°.
9) Valgus/Varus deformities 15-20°.
10) Valgus/Varus deformities 20-30°.

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: +49-40-53995
Contact Person:	Waldemar Link GmbH & Co. KG Stefanie Fuchs *(Regulatory Affairs)* Oststraße 4-10 22844 Norderstedt, Germany Phone: +49-40 53995-530 Fax: +49-40 53995-174 E-Mail: st.fuchs@linkhh.de Facility Registration: 3004371426
Date Prepared:	June 4, 2021
Trade Name:	LINK Endo-Model Total Knee System, Femoral Segments (Augments), UHMWPE
Common Name:	Artificial knee replacement system
Classification Name:	21 CFR §888.3510: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Classification and Panel:	Class II, Orthopedic / 87, KRO
Predicate Devices:	K143179: LINK Endo-Model Knee System by Waldemar Link GmbH & Co KG [Primary predicate] K151008, LINK Megasystem-C with Endo-Model SL Knee System, by Waldemar Link GmbH & Co KG K821476/S01: LINK Endo-Model Rotating Hinge Revision Knee System by Waldemar Link GmbH & Co KG, (original submission by CR Bard).
Reason for Submission	The submission adds the following accessory components: Femoral Segments (Augments) made of UHMWPE.
Device Description:	This 510k adds Femoral Segments (Augments) made of UHMWPE. The subject femoral segments are available in four heights: size 1 (20mm h), size 2 (25mm h), size 3 (50mm h), and size 4 (80mm h). They are available in right and left versions, and in sizes x-small, small, medium, and large, which correspond to the femoral component sizing. The size 1 and size 2 segments are a unicompartmental design provided either as a set containing one medial and one lateral component, or individually packaged (e.g. only the medial or only the lateral). The size 3 and 4 are a bicompartmental design (do not have medial versus lateral components like the size 1 and 2 variants).
Intended Use:	The LINK Endo-Model Knee System is indicated for patients with severe joint diseases with limitation of mobility due to degenerative, rheumatoid or post-traumatic arthrosis or arthritis. Joint fractures which disallow an osteosynthetic reconstruction. This device is intended for cemented use only unless a cementless modular stem is indicated for use.

The LINK Endo-Model Rotating Hinge and Modular Rotating Hinge Knee System are indicated for the following conditions:
1) Bone necroses.
2) Bicondylar arthrosis by partly damaged collateral ligaments
3) Revision after primary total knee replacement.
4) Revision surgery after hinge knee or rotational knee joint.
5) Revision surgery by insufficient / inadequate bone mass.
6) Arthrosis of patella flange.
7) Valgus/Varus deformities <10°.
8) Valgus/Varus deformities 10-15°.
9) Valgus/Varus deformities 15-20°.

The LINK® Endo-Model® Non-Rotating Hinge and Modular Non-Rotating Hinge Knee System are indicated for the following conditions:
1) Bone necroses.
2) Bicondylar arthrosis by completely damaged ligaments and muscular instability.
3) Revision after primary total knee replacement.
4) Revision surgery after hinge knee or rotational knee joint.
5) Revision surgery by insufficient / inadequate bone mass.
6) Arthrosis of patella flange.
7) Valgus/Varus deformities <10°.
8) Valgus/Varus deformities 10-15°.
9) Valgus/Varus deformities 15-20°.
10) Valgus/Varus deformities 20-30°.

Comparison to Predicate Device: The Endo-Model Knee System (K143179, K152431) includes femoral segments (augments) made of titanium for use with the Endo-Model Knee. This submission adds femoral segments made of UHMWPE for use with the Endo-Model Knee (K143179, K152431) that have the same designs as their corresponding femoral segments made of Ti6Al4V alloy. Prior LINK 510ks for other knee systems include femoral segments made of either Ti6Al4V or UHMWPE including: The Endo-Model SL (K151008) includes femoral segments made of titanium or UHMWPE for use with the Endo-Model SL Knee, and the Endo-Model Rotating Hinge Revision Knee (K821476/S01 from 1994) also includes femoral segments made of Ti6Al4V and UHMWPE in the same design variants, but in sizes S, M, and L (but not XS).

Performance Testing: A comparison of designs, materials, purpose, and fixation method was provided to demonstrate substantial equivalence to the predicate femoral augments.

An evaluation of the Biocompatibility of the modified device compared to the predicate UHMWPE augments was provided.

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

Conclusion: The predicate devices are legally marketed. The subject devices have the same intended uses as the predicate devices. Minor technological differences do not raise different questions of safety and effectiveness. Established scientific methods exist to evaluate the device performance, and the methods demonstrate the equivalence of the subject device to the predicate devices. Therefore, the determination of Substantial Equivalence is supported.