July 17, 2020

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

Re: K201364
Trade/Device Name: LINK® TrabecuLink® Femoral Cones
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH
Dated: May 22, 2020
Received: May 22, 2020

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.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201364

Device Name
LINK TrabecuLink Femoral Cones

Indications for Use *(Describe)*

The LINK TrabecuLink Femoral and Tibial Cones are indicated for patients with severe joint diseases with limitation of mobility due to degenerative, rheumatoid or post-traumatic arthrosis or arthritis and joint fractures which disallow an osteosynthetic reconstruction.

The LINK TrabecuLink Femoral and Tibial Cones are indicated for the following conditions:

- Surgeries which require implantation of a total knee endoprosthesis after severe degeneration or bone loss, traumata, or other pathologies.

The device is intended 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)
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
Date Prepared:	May 18, 2020
Trade Name:	*LINK*® TrabecuLink® Femoral Cones
Common Name:	Knee System Femoral Cones Augments
Classification Name:	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis; 21 CFR §888.3565, product code MBH
Classification and Panel:	Class II, Orthopedic / 87
Predicate Devices:	NexGen® Trabecular Metal™ Femoral Cone Augments (K103517) *[primary]*; *LINK*® TrabecuLink® Tibial Cones (K200113)
Reference Devices:	NexGen® Trabecular Metal™ Tibial Cone Augments (K102896)
Device Description:	The *LINK*® TrabecuLink® Femoral Cones are an extension to the *LINK*® TrabecuLink® Tibial Cones (K200113). The femoral cones are designed to be used in conjunction with the *LINK*® Endo-Model® Knee System Standard / Modular / Porex® coated (K143179; K152431) and with the Endo-Model® SL® Knee System (K151008) femoral components. The subject device is intended to fill large bone defects and stabilize the femoral bone structure in a joint replacement. The femoral cones are manufactured using an EBM (Electron Beam Melting) process with titanium alloy powder (Ti6Al4V). The femoral cones consist of a non-porous bulk interior surface and a trabecular structure made of titanium (*LINK*® TrabecuLink®) on the external surface.

The *LINK*® TrabecuLink® Femoral Cones provide cementless fixation to the bone. The mating knee endoprosthesis is cemented to the femoral cone.

Indications for Use:

The *LINK*® TrabecuLink® Tibial and Femoral Cones are indicated for patients with severe joint diseases with limitation of mobility due to degenerative, rheumatoid or post-traumatic arthrosis or arthritis and joint fractures which disallow an osteosynthetic reconstruction.

The *LINK*® TrabecuLink® Tibial and Femoral Cones are indicated for the following conditions:

- Surgeries which require implantation of a total knee endoprosthesis after severe degeneration or bone loss, traumata or other pathologies.

The device is intended for uncemented use.

Comparison to Predicate Device:

The *LINK*® TrabecuLink® Femoral Cones are substantially equivalent to the NexGen® Trabecular Metal™ Femoral Cone Augments (K103517). Both are manufactured from porous materials that are intended to fill defects in the femur during total knee replacement. The devices differ in regards to microstructure, materials and manufacturing methods, but these differences do not raise different safety or effectiveness concerns and have been addressed via biocompatibility assessment, non-clinical performance testing, and process validation. The microstructure of the porous regions has been characterized and assessed per coating testing. Further, the subject *LINK*® TrabecuLink® Femoral Cones are manufactured by the same process and material and have the same porous TrabecuLink surface as the predicate *LINK*® TrabecuLink® Tibial Cones (K200113).

Features comparable to the predicate devices include the same or similar indications, dimensions, materials, surgical implantation technique, and intended use.

Performance Data:

Non-Clinical Performance and Conclusions:

Non-clinical performance testing and analysis were provided, including bench testing and coating characterization. Specifically, the following tests were performed:

- Compression testing
- Dynamic fatigue testing

The following testing also applicable to the subject femoral cones was incorporated by reference to the predicate *LINK*® TrabecuLink® Tibial Cones submission K200113:

- Coating characterization included porosity, pore size, thickness measurements
- Static tensile testing of the porous material

- Static and dynamic shear testing of the porous material
- Abrasion testing of the porous material
- Pyrogenicity Testing

The results of non-clinical performance testing demonstrate that the device is as safe, as effective and substantially equivalent to the predicate devices.

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

Conclusion: The subject device *LINK*® TrabecuLink® Femoral Cones are substantially equivalent to the predicate and reference devices identified in this premarket notification.