



March 18, 2020

Waldemar Link GmbH & Co. KG  
Stefanie Fuchs  
Official Correspondent  
Oststrabe 4-10  
Norderstedt, 22844  
GERMANY

Re: K200113

Trade/Device Name: LINK TrabecuLink Tibial 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: January 17, 2020

Received: January 17, 2020

Dear Stefanie Fuchs:

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](mailto: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

**Indications for Use**

510(k) Number (if known)

K200113

Device Name

LINK® TrabecuLink® Tibial Cones

Indications for Use (Describe)

The LINK® TrabecuLink® 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® 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

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**510(k) Summary**

<b>510(k) Submitter:</b>	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)
<b>Contact Person:</b>	Waldemar Link GmbH & Co. KG Stefanie Fuchs ( <i>Regulatory Affairs</i> ) Oststraße 4-10 22844 Norderstedt, Germany Phone: +49-40 53995-530 Fax: +49-40 53995-174 E-Mail: st.fuchs@linkhh.de
<b>Date Prepared:</b>	January 15 <sup>th</sup> , 2020
<b>Trade Name:</b>	<i>LINK</i> <sup>®</sup> TrabecuLink <sup>®</sup> Tibial Cones
<b>Common Name:</b>	Knee System Tibial Cones Augments
<b>Classification Name:</b>	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis; 21 CFR §888.3565, product code MBH
<b>Classification and Panel:</b>	Class II, Orthopedic / 87
<b>Predicate Devices:</b>	NexGen <sup>®</sup> Trabecular Metal <sup>™</sup> Tibial Cone Augments by Zimmer Biomet Holdings, Inc., K102896, cleared December 13, 2010  Optetrak Logic <sup>®</sup> Metaphyseal Cones by Exactech, Inc., K153595, cleared March 25, 2016
<b>Device Description:</b>	The <i>LINK</i> <sup>®</sup> TrabecuLink <sup>®</sup> Tibial Cones are designed to be used in conjunction with the <i>LINK</i> <sup>®</sup> Endo-Model <sup>®</sup> Knee System Standard / Modular / Porex <sup>®</sup> coated (K143179; K152431) and with the Endo-Model <sup>®</sup> SL <sup>®</sup> Knee System (K151008) tibial components. The subject device is intended to fill small to medium bone defects and provide a stable platform for the tibial articulating components. The tibial cones are manufactured using an EBM (Electron Beam Melting) process with titanium alloy powder (Ti6Al4V, ISO 5832-3). The tibial cones consist of a non-porous bulk interior surface and a trabecular structure made of titanium ( <i>LINK</i> <sup>®</sup> TrabecuLink <sup>®</sup> ) on the external surface. The <i>LINK</i> <sup>®</sup> TrabecuLink <sup>®</sup> Tibial Cones provide cementless fixation to the bone. The subsequently implanted knee endoprosthesis is cemented to the tibial cone.
<b>Indications for Use:</b>	The <i>LINK</i> <sup>®</sup> TrabecuLink <sup>®</sup> 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*<sup>®</sup> TrabecuLink<sup>®</sup> 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.

**Comparison to Predicate Device:**

The *LINK*<sup>®</sup> TrabecuLink<sup>®</sup> Tibial Cones are substantially equivalent to Zimmer<sup>®</sup> NexGen<sup>®</sup> Trabecular Metal<sup>™</sup> Tibial Cone Augments (K102896) and Exactech<sup>®</sup> Optetrak Logic<sup>®</sup> Metaphyseal Cones (K153595). Both are manufactured from porous materials that are intended to fill defects in the tibia during total knee replacement. The devices differ in regards to microstructure, materials and manufacturing methods, but these differences do not raise difference safety or effectiveness concerns and have been addressed via a biocompatibility assessment and process validation. The microstructure of the porous regions has been characterized and assessed per coating testing. Further, the same EBM material has been seen in K153595.

Features comparable to the predicate devices include the same 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
- 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 device.

**Clinical Performance and Conclusions:**

There was no clinical performance testing required for this device.

**Conclusion:**

The subject device *LINK*<sup>®</sup> TrabecuLink<sup>®</sup> Tibial Cones are substantially equivalent to the predicate devices identified in this premarket notification.