May 3, 2022

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

Re: K220628
Trade/Device Name: LINK Endo-Model EVO Knee System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: March 4, 2022
Received: March 4, 2022

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,

For 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)*
K220628

Device Name
Link Endo-Model EVO Knee System, and Link OptiStems

Indications for Use *(Describe)*

General Indications LINK Endo-Model EVO Knee System:
The LINK Endo-Model EVO Knee System is intended for mobility limiting diseases, fractures or defects of the knee joint, distal femur or proximal tibia which cannot be treated by conservative or os- teosynthetic procedures.
This device is intended for cemented use only unless a cementless modular stem is indicated for use.
Indications:
All LINK Endo-Model EVO components:
• Primary and secondary osteoarthritis.
• Rheumatoid arthritis.
• Revision after primary or revision total knee replacement.
• Bone necroses which won't compromise the successful implantation of a hinged total knee endoprosthesis.
• Varus and valgus deformity with contracture or laxity of the medial or lateral stabilizers.
The LINK Endo-Model EVO Pure Hinge is additionally indicated for:
• Extreme cases of varus/valgus deformities (20-30°), rheumatoid arthritis, muscular deficiency and any kind of genu laxum.
• Oncological and revision surgery in lower limb (in conjunction with the Endo- Model EVO -W and the Megasystem-C)
The LINK Endo-Model EVO Rotating Hinge is additionally indicated for:
• Oncological and revision surgery in lower limb (in conjunction with the Endo- Model EVO -W and the Megasystem-C)

General Indications Link OptiStems:
The Link OptiStems are for use with the following LINK knee femoral components, both intracondylar and distal femoral replacement versions: LINK Endo-Model SL, LINK Endo-Model EVO-M, and LINK Endo-Model EVO-W and are indicated for mobility limiting diseases, fractures or defects of the knee joint, distal femur or proximal tibia which cannot be treated by conservative or osteosynthetic procedures.
The Link OptiStems cemented are intended for cemented use only. The Link OptiStems cementless are intended for cementless use only.
Indications:
• Revision arthroplasty due to juxta-articular bone defects.
• Revision of loosened femoral prosthesis components by peri-/subprosthetic fracture.
• Bone deficiencies, e.g. due to tumors, as well as in large post-revision and posttrauma segmental bone defects.
• Oncological and revision surgery in the area of the distal femur (in conjunction with Endo-Model SL Rotational and Hinge Knee Prostheses or LINK Endo-Model EVO – M/ – W).

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: March 3, 2022

Trade Name: LINK Endo-Model EVO Knee System

Common Name: Knee Joint Replacement

Classification Name: 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 Endo-Model Knee System: K143179

Additional Predicates
Waldemar Link LINK Endo-Model Knee System with PorEx (TiNbN) coating: K152431, K212742
Waldemar Link LinkSymphoKnee: K202924
Waldemar Link LINK MEGASYSTEM-C: K151008

Device Description:

The LINK Endo-Model EVO Knee System is available in multiple versions with different applications, characteristics, and materials.

The LINK Endo-Model EVO is a constrained total knee prosthesis, which is based on the previously cleared LINK Endo-Model Knee System (K143179, K152431, K212742), and is considered an evolution ('EVO') of the previous designs. The Knee System is available in two different hinge designs - Rotating Hinge and Non-rotating (Pure) Hinge.

Also like the previously cleared system, the subject LINK Endo-Model EVO is available in two versions – LINK Endo-Model EVO Standard and LINK Endo-Model EVO – Modular. The femoral and

tibial components of the standard version have fixed stems while the femoral and tibial components of the modular system are available with stems having a taper connection. The modular system includes femoral components with either a male taper or a female taper, and are designated as LINK Endo-Model EVO-M (male taper) and Endo-Model EVO-W ("weiblich" = female taper).

The LINK Endo-Model EVO – Standard consists of a cemented monoblock femoral component made from CoCrMo and cPE and a cemented monoblock tibial component made from CoCrMo and an articulating surface made from cPE. The Standard System is available in Rotating Hinge or Pure Hinge.

The LINK Endo-Model EVO – M consists of a cemented modular femoral component made from CoCrMo, Ti6Al4V (Tilastan) and cPE and a cemented modular tibial component made from CoCrMo, Ti6Al4V (Tilastan) and an articulating surface made from cPE and with modular stems, cemented made from CoCrMo or cementless made from Ti6Al4V (Tilastan). The Modular System is available in Rotating Hinge or Pure Hinge.

The LINK Endo-Model EVO – W intracondylar and condylar replacements consists of a cemented modular femoral component made from CoCrMo, Ti6Al4V (Tilastan) and cPE and a cemented modular tibial component made from CoCrMo, Ti6Al4V (Tilastan) and an articulating surface made from cPE and with modular stems, cemented made from CoCrMo or cementless made from Ti6Al4V (Tilastan). The Modular System is available in Rotating Hinge or Pure Hinge.

The femoral components can be used with distal and femoral (straight and L-shaped) segments made from Ti6Al4V (Tilastan).

The modular tibial components can be used with tibial spacers made from Ti6Al4V (Tilastan).

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

Additionally a 3-peg patella can be used with the LINK Endo-Model EVO Knee System. It is made from cPE.

The LINK Endo-Model EVO Knee System femoral and tibial components are compatible with the previously cleared LINK Endo-Model Knee System (K143179, K152431 and K212742).

The femoral components of the LINK Endo-Model EVO – W are compatible with the previously cleared LINK MEGASYSTEM-C (K151008).

The LINK Endo-Model EVO Knee System is compatible with previously cleared Tibial and Femoral Cones of Waldemar Link GmbH & Co. KG (K200113 and K201364).

The Link OptiStems are an expansion of the modular stem portfolio. The Link OptiStems consist of a modular stem, adapter and fixation screw. The Link OptiStems come in cemented and cementless version. The Link OptiStems have to be joined and implanted in combination with the Femoral Components of LINK Endo-Model SL (K151008) or LINK Endo-Model EVO – M / -W.

Indications for Use:

General Indications LINK Endo-Model EVO Knee System:

The LINK Endo-Model EVO Knee System is intended for mobility limiting diseases, fractures or defects of the knee joint, distal femur or proximal tibia which cannot be treated by conservative or osteosynthetic procedures.

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

Indications:

All LINK Endo-Model EVO components:

- Primary and secondary osteoarthritis.
- Rheumatoid arthritis.
- Revision after primary or revision total knee replacement.
- Bone necroses which won‘t compromise the successful implantation of a hinged total knee endoprosthesis.
- Varus and valgus deformity with contracture or laxity of the medial or lateral stabilizers.

The LINK Endo-Model EVO Pure Hinge is additionally indicated for:

- Extreme cases of varus/valgus deformities (20-30°), rheumatoid arthritis, muscular deficiency and any kind of genu laxum.
- Oncological and revision surgery in lower limb (in conjunction with the Endo- Model EVO -W and the Megasystem-C)

The LINK Endo-Model EVO Rotating Hinge is additionally indicated for:

- Oncological and revision surgery in lower limb (in conjunction with the Endo- Model EVO -W and the Megasystem-C)

General Indications Link OptiStems:

The Link OptiStems are for use with the following LINK knee femoral components, both intracondylar and distal femoral

replacement versions: LINK Endo-Model SL, LINK Endo-Model EVO-M, and LINK Endo-Model EVO-W and are indicated for mobility limiting diseases, fractures or defects of the knee joint, distal femur or proximal tibia which cannot be treated by conservative or osteosynthetic procedures.

The Link OptiStems cemented are intended for cemented use only. The Link OptiStems cementless are intended for cementless use only.

Indications:

- Revision arthroplasty due to juxta-articular bone defects.
- Revision of loosened femoral prosthesis components by peri-/subprosthetic fracture.
- Bone deficiencies, e.g. due to tumors, as well as in large post-revision and posttrauma segmental bone defects.
- Oncological and revision surgery in the area of the distal femur (in conjunction with Endo-Model SL Rotational and Hinge Knee Prostheses or LINK Endo-Model EVO – M/ – W).

Comparison to the predicate: The LINK Endo-Model EVO Knee System is substantially equivalent to the commercially available device LINK Endo-Model Knee System 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)

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 LINK Endo-Model EVO Knee System is substantially equivalent to the predicate devices identified in this premarket notification.