September 16, 2021

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

Re: K212742
Trade/Device Name: GEMINI SL Total Knee System, Endo-Model Knee System with LINK PorEx (TiNbN) coating, Sled Knee System with LINK PorEx (TiNbN) coating
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, KRO, HSX
Dated: September 1, 2021
Received: September 1, 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)*
K212742

Device Name
GEMINI SL Total Knee System

Indications for Use *(Describe)*
The GEMINI SL Total Knee System is indicated for patients suffering from disability due to:
1) Degenerative, post-traumatic or rheumatoid arthritis;
2) Avascular necrosis of the femoral condyle;
3) Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
4) Moderate valgus, varus or flexion deformities.

This device may also be indicated in the salvage of previously failed surgical attempts.
The device is indicated for cemented use. Only cementless labeled modular stems are indicated 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.

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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:

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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)*
K212742

Device Name
Endo-Model Knee System with LINK PorEx (TiNbN) coating and Sled Knee System with LINK PorEx (TiNbN) coating

Indications for Use *(Describe)*
The Endo-Model and Sled Knee Systems with LINK PorEx (TiNbN) coating are 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. These devices are intended for cemented use only.

The Endo-Model Rotating Hinge and Modular Rotating Hinge Knee System with LINK PorEx (TiNbN) coating 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 Sled Knee System with LINK PorEx (TiNbN) coating is indicated for the following conditions:
1) Unicondylar arthrosis by intact ligaments including both cruciate ligaments
2) Valgus/Varus deformities <10°

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 – LINK PorEx (TiNbN) inhouse coating
for Endo-Model Knee System, Sled Knee System, and GEMINI SL Total Knee System

510(k) Submitter:	Waldemar Link GmbH & CO. KG Barkhausenweg 10 22339 Hamburg, Germany Phone: +49-40-539950 Facility Registration #:3004371426 (Oststraße 4-10)
Contact Person:	Waldemar Link GmbH & Co. KG Lydia Ditter *(Regulatory Affairs)* Oststraße 4-10 Norderstedt, GERMANY 22844 Phone: +49-40 53995-530 Fax: +49-40 53995-174 E-Mail: L.Ditter@linkhh.de
Date Prepared:	September 15, 2021
Trade Name:	GEMINI SL Total Knee System Endo-Model Knee System with LINK PorEx (TiNbN) coating Sled Knee System with LINK PorEx (TiNbN) coating
Common Name:	Total Knee Prosthesis
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis; 21 CFR §888.3560, product code JWH Knee joint femorotibial metal/polymer constrained cemented prosthesis; 21 CFR §888.3510, product code KRO Knee joint femorotibial metal/polymer non-constrained cemented prosthesis; 21 CFR §888.3520, product code HSX
Classification and Panel:	Class II, Orthopedic / 87
Predicate Devices:	Primary Predicate: GEMINI SL Total Knee System, K182872 Endo-Model Knee System with PorEx (TiNbN) coating, Sled Knee System with PorEx (TiNbN) coating, K152431

Reference Predicate:
LinkSymphoKnee System, K202924

Device Description:

The GEMINI SL Total Knee System is a semi-constrained, patellofemorotibial, cemented knee prosthesis. It is intended to replace the three articular portions of the knee joint.
The system compromises two different designs: "Cruciate Retaining (CR)" and "Posterior Stabilized (PS)".
Both versions consist of similar components: a Cobalt Chromium femoral component a polyethylene patella and a Cobalt Chromium tibial baseplate with an Ultra High Molecular Weight Polyethylene (UHMWPE / non-crosslinked) insert. The fixation of the tibial baseplate can be extended due to modular stems. The femoral and tibial components are made of CoCrMo and are available with PorEx surface modification.

The Endo-Model Knee System with LINK PorEx (TiNbN) coating is a constrained anti-luxation total knee prosthesis.

The Endo-Model Knee System consists of femoral and tibial components and modular stems. The modular stems are available in a variety of diameters and lengths in cemented version.
The Endo-Model Knee System is available in two (2) different knee joint versions:

- Rotating Hinge Knee – Standard (Non-Modular) Version
- Rotating Hinge Knee – Modular Version

The Endo-Model Knee System is produced of Cobalt Chromium Molybdenum casting alloy (CoCrMo) and Ultra high molecular weight polyethylene (UHMWPE / non-crosslinked). The modular stems (cemented) are made of Cobalt Chromium Molybdenum casting alloy (CoCrMo) materials.

The Sled Knee System with LINK PorEx (TiNbN) coating is a unicompartmental non-constrained knee replacement system. The Sled Knee is comprised of a set of implants and consists of a femoral component and a tibial component (all-polyethylene or metal-backed) and are available in different sizes.
The femoral implant is made of Cobalt Chromium Molybdenum casting alloy (CoCrMo) and is personalized to match a patient's anatomy.

The all-poly tibial component is made from Ultra high molecular weight polyethylene (UHMWPE / non-crosslinked) and forgeable and cold-formed cobalt-chromium-nickel molybdenum-iron alloy (CoCrNiMoFe) X-ray wire. The metal-backed tibial component consists of a Cobalt Chromium Molybdenum casting alloy (CoCrMo) tibial tray and with an Ultra high molecular weight polyethylene (UHMWPE / non-crosslinked) tibial insert and cold-formed cobalt-chromium-nickel molybdenum-iron alloy (CoCrNiMoFe) X-ray wire.
Multiple inserts of varying thickness may be provided to accommodate surgeon preferences.

The change that is the subject of this Special 510(k) is to add the coating of Titanium Niobium Nitride (TiNbN) done by Waldemar Link inhouse to the above listed systems. The devices are already commercially available with TiNbN coating applied by an external vendor.
There is no change to the fundamental scientific technology of the referenced knee systems with the modifications in this 510(k) submission. This includes no changes to materials, design, sterilization, packaging, or method of manufactured.
All components are sterile and for single use only.

Indications for Use:

The GEMINI SL Total Knee System is indicated for patients suffering from disability due to:

- Degenerative, post-traumatic or rheumatoid arthritis;
- Avascular necrosis of the femoral condyle;
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
- Moderate valgus, varus or flexion deformities.

This device may also be indicated in the salvage of previously failed surgical attempts.
The device is indicated for cemented use. Only cementless labeled modular stems are indicated for uncemented use.

The Endo-Model and Sled Knee Systems with LINK PorEx (TiNbN) coating are 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. These devices are intended for cemented use only.

The Endo-Model Rotating Hinge and Modular Rotating Hinge Knee System with LINK PorEx (TiNbN) coating 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 Sled Knee System with LINK PorEx (TiNbN) coating is indicated for the following conditions:

1) Unicondylar arthrosis by intact ligaments including both cruciate ligaments
2) Valgus/Varus deformities <10°

Comparison to Predicate Device:

The GEMINI SL Total Knee System with LINK PorEx (TiNbN) inhouse coating is substantially equivalent to GEMINI SL Total Knee System (#K182872)

The Endo-Model and Sled Knee Systems with LINK PorEx (TiNbN) inhouse coating are substantially equivalent to Endo-Model and Sled Knee Systems with PorEx (TiNbN) coating (#K152431).

The only change of the subject knee systems is the PorEx coating applied inhouse, which is substantially equivalent to the LINK PorEx inhouse coating applied on the LinkSymphoKnee System previously cleared in #K202924.

Performance Data:

Non-Clinical Performance and Conclusions:

There was no additional non-clinical performance testing required for the devices in scope.

System specific testing, with consideration to *Draft Guidance For The Preparation of Premarket Notifications (510(k)s) for cemented, semi-constrained Total Knee Prostheses* can be found in predicate 510(k)s #K152431 and #K182872.

Testing considering the LINK PorEx (TiNbN) inhouse coating was done in **#**K202924

Clinical Performance and Conclusions:

	There was no clinical performance testing required for this device.
Conclusion:	The subject devices Gemini SL Total Knee System, Endo-Model and Sled Knee Systems with LINK PorEx (TiNbN) inhouse coating are substantially equivalent to the predicate devices identified in this premarket notification.