DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Waldemar Link Gmbh & Company KG
Andre Von Malotki
Regulatory Affairs
Barkhausenweg 10
Hamburg, 22339
GERMANY

May 9, 2016

Re: K152431
Trade/Device Name: LINK® Endo-Model® Knee System with PorEx® (TiNbN) coating,
LINK® Sled Knee System with PorEx® (TiNbN) coating
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO, HSX
Dated: April 15, 2016
Received: April 19, 2016

Dear Mr. Von Malotki:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152431

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

Indications for Use *(Describe)*
The LINK® Endo-Model® and Sled Knee Systems with 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 LINK® Endo-Model® Rotating Hinge and Modular Rotating Hinge Knee System with 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 LINK® Sled Knee System with 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

510(k) Submitter:

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Date Prepared:

August 24th, 2015

Trade Name:

LINK® Endo-Model® Knee System with PorEx® (TiNbN) coating and *LINK*® Sled Knee System with PorEx® (TiNbN) coating

Common Name:

Total Knee Prosthesis

Classification Name:

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:

Foundation Knee System with TiNbN coating; Foundation PS Knee System with TiNbN coating; 3D Knee System with TiNbN coating by DJO Surgical, K122239, cleared April 11, 2013

LINK® Endo-Model® Knee System, K143179, cleared January 30, 2015

LINK® Sled Uni-Compartment Knee System, K954186, cleared January 26, 1996

Device Description:

The *LINK*® Endo-Model® Knee System is constrained anti-luxation total knee prosthesis.
Retaining the low friction principle, the physiological movement of the rotational knee prosthesis is optimal because the pivot point is within the physiological area.

Flexion and rotation of the rotational knee prosthesis take place in a cross joint.
The *LINK*® 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 *LINK*® 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 *LINK*® 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 *LINK*® Sled Knee is a unicompartmental non-constrained knee replacement system. The *LINK*® 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 510(k) is to add the coating of Titanium Niobium Nitride (TiNbN) to the entire surface of the above listed components.
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 *LINK*® Endo-Model® and Sled Knee Systems with 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 *LINK*® Endo-Model® Rotating Hinge and Modular Rotating Hinge Knee System with 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
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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*® Sled Knee System with 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 *LINK*® Endo-Model® and Sled Knee Systems with TiNbN coating is substantially equivalent to *LINK's* Endo-Model® Knee System (K143179) and Sled Knee System (K954186). The TiNbN coating is the only change to the previous cleared Knee Systems. Furthermore, they are also substantially equivalent to the commercially available device Foundation Knee System with TiNbN coating; Foundation PS Knee System with TiNbN coating (K122239) in that both have same material and coating. Features comparable to the

predicate devices include the same indications, dimensions, materials, packaging, sterilization, surgical implantation technique and intended use.

Performance Data:

Non-Clinical Performance and Conclusions:

Non-Clinical performance testing was conducted with consideration to *Draft Guidance For The Preparation of Premarket Notifications (510(k)s) for cemented, semi-constrained Total Knee Prostheses, April 1993, Guidance Document for Knee Joint patellofemorotibial and femorotibial metal/polymer porous-coated uncemented Prostheses, January 16, 2003*

Non-clinical performance testing included: Tibial Bearing Component wear test per ISO 14243-1 and -2; Particles Analyses test per ISO 17853 and ASTM F1877; Modular Connections, Fretting, and Corrosion Testing per ASTM F1875-98; and Range of Motion analyses of the *LINK*® Endo-Model® and Sled Knee Systems; Coating Chemical Composition; Coating Thickness; Coating Hardness; Adhesion Strength and Roughness

Non-clinical biocompatibility testing included: Acute System Toxicity Study; Bone Implantation Study; Cytotoxicity Study; GC/MS Fingerprint Study; Irritation Study; Sensitization Study; 28 Day Muscle Implantation Study; 90 Day Muscle Implantation Study

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 devices *LINK*® Endo-Model® and Sled Knee Systems with PorEx® (TiNbN) coating are substantially equivalent to the predicate devices identified in this premarket notification.