DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Waldemar Link GmbH & Company KG
Ms. Stefanie Reimers
Regulatory Affairs
Barkhausenweg 10
22339 Hamburg
Germany

August 26, 2015

Re: K151008
Trade/Device Name: Link® Megasystem-C®
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO, LZO, JDI, LWJ
Dated: July 23, 2015
Received: July 24, 2015

Dear Ms. Reimers:

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 Part 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" (21 CFR 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 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)*

Device Name
LINK® MEGASYSTEM-C®

Indications for Use *(Describe)*
The LINK® MEGASYSTEM-C® is intended to be used with the components of the Endo-Model® SL® Rotating and Non-Rotating Hinge Knee or Endo-Model® Knee System (#K143179) which can be integrated for knee joint replacement and with the MP® Reconstruction Prosthesis (#K142187) for hip replacement.

The LINK® MEGASYSTEM-C® is indicated for treatment of any of the following Limb salvage/Oncology procedures:

1) Revision for loosened femoral prosthesis components involving extensive bone loss;
2) Surgical intervention for severe trauma;
3) Oncology cases where extensive resection and replacement of bone is required from tibia to hip area;

The device is to be used with bone cement unless a proximal femur or a modular stem is indicated for use.

For the use of the LINK® Endo-Model® SL® Rotating and Non-Rotating Hinge Knee System additional indications should be noted:
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°.

For the use of the LINK® Endo-Model® SL® Non-Rotating Hinge Knee System additional indications should be noted:
10) Bicondylar arthrosis by completely damaged collateral ligaments and muscular instability.
11) Valgus/Varus deformities 20-30°.

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

510(k) Submitter:

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Date Prepared:

April 14th, 2015

Trade Name:

LINK® MEGASYSTEM-C®

Common Name:

Total Knee and Hip Revision Prosthesis

Classification Name:

Knee joint femorotibial metal/polymer constrained cemented prosthesis; 21 CFR §888.3510, product code KRO

Hip joint metal/ceramic/polymer semi-constraint cemented or nonporous uncemented;
21 CFR §888.3353, product code LZO

Hip joint metal/polymer semi-constrained cemented prosthesis; 21 CFR §888.3350, product code JDI

Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis; 21 CFR §888.3360, product code LWJ

Classification and Panel:

Class II, Orthopedic / 87

Predicate Devices:

GMRS™ Global Modular Replacement System, manufactured by Stryker, K023087, cleared December 16, 2002

Device Description:

The *LINK*® MEGASYSTEM-C® is comprised of a number of components that are intended to be used in conjunction with each other, or in conjunction with components of *LINK*® Endo-Model® SL® Rotating and Non- Rotating Hinge Knee, *LINK*® Endo-Model® Knee System (#K143179) and *LINK*® MP® Reconstruction Prosthesis (#K142187).

There are three (3) modules of the MEGASYSTEM-C®:

- Proximal Femur
- Distal Femur / Proximal Tibia
- Total Femur

Proximal Femur:
The Proximal Femur Module of the MEGASYSTEM-C® contains the following components:

- Proximal Femoral Components (Neck segments)
- Coupling Components
- Support Ring, Terminals
- Stem Segments
- Modular Stems

Distal Femur / Proximal Tibia:
The Distal Femur / Proximal Tibia Module of the MEGASYSTEM-C® contain the following components:

- Distal Femoral Components
- Femoral Components
- Femoral Segments
- Support Ring, Terminals
- Stem Segments
- Connection Components (rotating and non-rotating hinge)
- Proximal Tibial Components (Tibial plateau)
- Tibial Components (Tibial plateau)
- Proximal Tibial Spacers
- Modular Stems
- Coupling for diaphyseal spacer
- Coupling Components – Knee Fusion Nail, modular

Total Femur
Replacement of the Total Femur is accomplished by combining the following components of the MEGASYSTEM-C®:

- Proximal Femoral Components (Neck segments)
- Coupling Components
- Distal Femoral Components
- Connecting Components (rotating and non-rotating hinge)
- Stem Segments
- Proximal Tibial Components (Tibial plateau)
- Tibial Components (Tibial plateau)
- Modular Stems
- Push-through Stems

Due to its high modularity, the system allows partial bone replacements both in the proximal and distal femur in small increments as well as a total replacement of the femur. For the knee joint components, the Endo-Model® SL® Rotating Hinge Knee is used in the MEGASYSTEM-C®.

The *LINK*® MEGASYSTEM-C® is produced of Cobalt Chromium Molybdenum casting alloy (CoCrMo) and Ultra high molecular weight polyethylene (UHMWPE/non-crosslinked). The Modular Stems (cemented) and the Push-through stems are made of Cobalt Chromium Molybdenum casting alloy (CoCrMo) materials. The Modular Stems (cementless) are made of Titanium-Aluminum-Vanadium alloy (Ti-6Al-4V) materials.
Stem Segments, Coupling for diaphyseal spacer and Support Ring are produced of Titanium-Aluminum-Vanadium alloy (Ti-6Al-4V). Coupling components and the knee fusion nail are made of Cobalt Chromium Molybdenum casting alloy (CoCrMo) materials.
Femoral Segments and Proximal Tibial Spacers are produced of Titanium-Aluminum-Vanadium alloy (Ti-6Al-4V) and respectively of Ultra high molecular weight polyethylene (UHMWPE/non-crosslinked).

Indications for Use:

The *LINK*® MEGASYSTEM-C® is intended to be used with the components of the Endo-Model® SL® Rotating and Non-Rotating Hinge Knee or Endo-Model® Knee System (#K143179) which can be integrated for knee joint replacement and with the MP® Reconstruction Prosthesis (#K142187) for hip replacement.

The *LINK*® MEGASYSTEM-C® is indicated for treatment of any of the following Limb salvage/Oncology procedures:

1) Revision for loosened femoral prosthesis components involving extensive bone loss;
2) Surgical intervention for severe trauma;
3) Oncology cases where extensive resection and replacement of bone is required from tibia to hip area;

The device is to be used with bone cement unless a proximal femur or a modular stem is indicated for use.

For the use of the *LINK*® Endo-Model® SL® Rotating and Non-Rotating Hinge Knee System additional indications should be noted:

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°.

For the use of the *LINK*® Endo-Model® SL® Non-Rotating Hinge Knee System additional indications should be noted:

10) Bicondylar arthrosis by completely damaged ligaments and muscular instability.
11) Valgus/Varus deformities 20-30°.

Comparison to Predicate Device:

The *LINK*® MEGASYSTEM-C® is substantially equivalent to the commercially available device GMRS™ Global Modular Replacement System in that both have same intended use and similar indications, design, materials, technological characteristics, and principles of operation. The minor technological differences between the *LINK*® MEGASYSTEM-C® and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the *LINK*® MEGASYSTEM-C® is as safe and effective as the GMRS™ Global Modular Replacement System. Both devices are intended for cemented use. In addition the *LINK*® MEGASYSTEM-C® provides cementless modular stems. Thus, the *LINK*® MEGASYSTEM-C® is substantially equivalent.

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 and Guidance for Industry and FDA Staff, Non-Clinical Information for Femoral Stem Prosthesis, September 17, 2007.*

Non-clinical performance testing included: Tibial Bearing Component wear test per ISO 14243-1 and -2 including tibiofemoral contact area / stress analyses at different angles of flexion; Tibial Baseplate Component fatigue test per ISO

14879 and ASTM F1800; femoral neck segment fatigue test per ISO 7206-6; femoral stem fatigue test per ISO 7206-4; proximal femoral components fatigue test per ASTM F2580; Modular Connections, Fretting, and Corrosion Testing per ASTM F1875-98; and Range of Motion analyses of the MEGASYSTEM-C® and Endo-Model® SL® Knee System.

Constraint testing is not applicable to a constrained prosthesis. This test was not necessary.

All Endo-Model® SL® Knee System test samples completed the 10 million cycles Tibial Baseplate Fatigue Strength testing without evidence of fracture or cracking.

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*® MEGASYSTEM-C® is substantially equivalent to the predicate device identified in this premarket notification.