July 18, 2019

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

Re: K191755
Trade/Device Name: SPAR-K Instruments (for use with Gemini SL Total Knee System)
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
Dated: July 1, 2019
Received: July 1, 2019

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 CAPT Raquel Peat, PhD, MPH, USPHS
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191755

Device Name

SPAR-K Instruments (for use with Gemini SL Total Knee System)

Indications for Use *(Describe)*
The LINK 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 intended 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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Special 510(k) Summary

510(k) Submitter:
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69 King Street
Dover, NJ 07801
973-625-1333 x112

Date Prepared: June 27, 2019

Proprietary Name: SPAR-K Instruments (for LINK GEMINI SL Total Knee System)

Common Name: Total Knee Prosthesis (Accessory Instruments)

Classification Name: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (888.3560, JWH, Class II)

Predicate Device(s): LINK GEMINI SL Total Knee System Gemini SL Instruments (510(k) #K182872)

Device Description: The SPAR-K instruments are a line extension to the instrument system cleared in 510(k) #K182872 with the Gemini SL Total Knee System. The SPAR-K instruments are manual orthopedic surgical reusable instruments offered to aid the implantation of the Gemini SL Total Knee System (K182872). The SPAR-K Instruments incorporate design changes for simplicity of use. The modifications do not significantly alter the surgical workflow or technique. Both the original and modified (SPAR-K) instruments accommodate tibia first or femur first workflows according to surgeon preference. The modifications do not change the intended use, or involve any change in technology. The Class II accessory instruments within the SPAR-K Instrument system that are the subjects of this 510(k) are the femoral, tibial, and patellar resection guides.

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

Special 510(k) Summary

- 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 intended for cemented use. Only cementless labeled modular stems are indicated for uncemented use.

Technological Characteristics and Substantial Equivalence

The modified Class II accessory instruments within the SPAR-K Instrument system that are the subjects of this 510(k) have the same intended use, operating principle, basic device designs and purposes, and materials as the unmodified instruments. The modified cutting guides create the same bone cuts, but feature minor design changes for simplicity and ease of use. A comparison of designs and features supported the substantial equivalence of the modified to the original instruments. Non-clinical and clinical performance testing were not required to demonstrate substantial equivalence.

Conclusion

The subject SPAR-K Instruments that are the subjects of this 510(k) (Class II accessory instruments) are Substantially Equivalent to the predicate instruments identified in this premarket notification.