October 25, 2019

Link Bio Corp.
Terry Powell
Regulatory Affairs Program Director
101 Roundhill Drive
Rockaway, New Jersey 07866

Re: K190181
Trade/Device Name: Instruments for LINK® MEGASYSTEM-C® Family
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRO, LWJ, LZO, JDI
Dated: September 30, 2019
Received: October 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 Ting Song, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190181

Device Name
Instruments for LINK® MegaSystem-C® Family

Indications for Use *(Describe)*
The Instruments for LINK MEGASYSTEM-C Family are intended to aid in intra-operative implantation of the LINK® MEGASYSTEM-C® (K151008), which can be integrated with the components of the Endo-Model® SL® Rotating and Non- Rotating Hinge Knee or Endo-Model® Knee System (#K143179) for knee replacement, and with the MP® Reconstruction Prosthesis (#K142187) for hip replacement. The LINK® MEGASYSTEM-C® (K151008), has the following indications:
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 surgery after primary total knee replacement.
4) Revision surgery after rotating or non-rotating hinged knee replacement.
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°.

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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510(k) Summary

510(k) Submitter:	Link Bio Corp. 69 King Street Dover, NJ 07801 Establishment Registration: 3006721341
Contact Person:	Terry Powell Regulatory Affairs Program Director Phone: 973-625-1333, x112 Fax: 973-625-4445 E-Mail: terry@linkbio.com
Date Prepared:	January 31, 2019
Trade Name:	Instruments for LINK® MEGASYSTEM-C® Family
Common Name:	Orthopedic Manual Reusable Surgical Instruments (Accessory Instruments to Hip and Knee Implant Systems)
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 Device:	Accessory Instruments for LINK® MEGASYSTEM-C®, Endo-Model® SL® Rotating and Non- Rotating Hinge Knee (K151008), LINK® Endo-Model® Knee System (#K143179) and LINK® MP® Reconstruction Prosthesis (#K142187).
Purpose:	Duplicate 510k and line extension filed by Link Bio Corp. for the accessory instruments previously cleared in K151008 by Waldemar Link GmbH & Co KG.
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). This is a duplicate 510k and line extension in Link Bio Corp.'s name for the accessory instrument system previously cleared in K151008 by Waldemar Link GmbH & Co KG for use with/as accessories to the LINK® MEGASYSTEM-C® and 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). It includes the same instruments as in K151008, and additional accessory instruments (line extension).
Indications for Use	The Instruments for LINK MEGASYSTEM-C Family are intended to aid in intra-operative implantation of the LINK® MEGASYSTEM-C® (K151008), which can be integrated with the components of the Endo-Model® SL® Rotating and Non-Rotating Hinge Knee or Endo-Model® Knee System (#K143179) for knee replacement, and with the MP® Reconstruction Prosthesis (#K142187) for hip replacement. The LINK® MEGASYSTEM-C® (K151008), has the following indications: 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 surgery after primary total knee replacement. 4) Revision surgery after rotating or non-rotating hinged knee replacement. 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°.
Performance Data:	Extensive performance testing was provided in K151008 for the implant system, but is not required for the accessory instruments.
Technological characteristics:	The accessory instruments presented in K151008 are exactly replicated in this duplicate 510k. Additional reusable manual surgical instruments included as a line extension are for the same purpose (to support implantation of the same Waldemar Link GmbH implant systems) as the existing instrument system, with no significant differences in technological features, materials, or intended use.
Basis of substantial equivalence:	This 510k is a duplicate in Link Bio Corp.'s name for the accessory instrument system previously cleared in K151008 by its sister company, Waldemar Link GmbH The subject instruments are either identical to those submitted previously in K151008, or represent minor design modifications (line extension) that do not change the intended use of the associated implant system, or represent significant changes to the accessory instruments system.