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

November 18, 2021

Re: K212992
Trade/Device Name: LINK® Embrace Shoulder System - Reverse Configuration
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented rosthesis
Regulatory Class: Class II
Product Code: PHX, HSD, PAO
Dated: September 20, 2021
Received: September 20, 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,

For Jiping Chen, Ph.D., M.P.H.
Acting Division 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)*
K212992

Device Name
LINK® Embrace Shoulder System - Reverse Configuration

Indications for Use *(Describe)*
General indications:
The LINK Embrace Shoulder System - Reverse Configuration is intended for reverse total shoulder arthroplasty.

Indications:
Primary, fracture, or revision total shoulder arthroplasty in a grossly rotator cuff deficient joint with severe arthropathy. A functional deltoid muscle is necessary, and the patient's joint must be anatomically and structurally suited to receive the implants.

The Reverse Glenoid Baseplate component is intended for cementless fixation with the addition of bone screws.
The Humeral Stems Standard with CaP (HX) and Short with CaP (HX) are intended for cementless fixation.
The Humeral Stems Standard without CaP (HX) and Short without CaP (HX) are intended for cemented or cementless fixation.
The Humeral Fracture Stems and Proximal Bodies are intended for cemented or cementless fixation.
The Modular Stems 75mm are intended for cemented or cementless fixation.
The Modular Stems, fully corundum blasted, are intended for cementless fixation.
The Modular Stems, fully polished, are intended for cemented fixation.

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:	Waldemar Link GmbH & Co. KG Barkhausenweg 10 22339 Hamburg, Germany Phone: +49-40-539950 Facility Registration: 3003386935
Contact Person:	LinkBio Corp. Terry Sheridan Powell *(Regulatory Affairs)* LinkBio Corp. 69 King Street Dover, NJ 07801 E-Mail: t.powell@linkbio.com
Date Prepared:	November 17, 2021
Trade Name:	LINK® Embrace Shoulder System - Reverse Configuration
Common Name:	Artificial Shoulder Joint Replacement
Classification Name:	21 CFR §888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis PHX: Shoulder Prosthesis, Reverse Configuration PAO: Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer + Additive, Cemented 21 CFR §888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis HSD Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented
Classification and Panel:	Class II, Orthopedic / 87
Predicate Devices:	Waldemar Link GmbH & Co KG LINK Embrace Total Shoulder System – Reverse Configuration [K200368 – Primary Predicate] Lima Corp. SMR Reverse Shoulder System [K110598]: Additional 510ks for the system include K100858, K101263 Integra Titan Reverse Shoulder System K173717, K181999, K190588
Reason for Submission	Adds Modular Humeral Stem Components to the predicate Embrace Total Shoulder System
Device Description:	This system adds modular humeral stem components to the LINK Embrace Shoulder System – Reverse Configuration, comprised of Proximal Bodies and Modular Stems. The modular Proximal Bodies (Ti6A4V) are available in several sizes and heights. The Proximal Bodies feature a spiked surface, and m-l and a-p holes for suture fixation. The Proximal Bodies feature a proximal modular taper

connection for assembly to the existing Reverse Tray components. The Proximal Bodies feature a distal modular taper connection for assembly to a modular stem.

The modular stems (Ti6Al4V) are available in different diameters and lengths as well as different surface options for cemented or cementless fixation.

Intended Use:

General indications:

The LINK Embrace Shoulder System - Reverse Configuration is intended for reverse total shoulder arthroplasty.

Indications:

Primary, fracture, or revision total shoulder arthroplasty in a grossly rotator cuff deficient joint with severe arthropathy. A functional deltoid muscle is necessary, and the patient's joint must be anatomically and structurally suited to receive the implants.

The Reverse Glenoid Baseplate component is intended for cementless fixation with the addition of bone screws.
The Humeral Stems Standard with CaP (HX) and Short with CaP (HX) are intended for cementless fixation.
The Humeral Stems Standard without CaP (HX) and Short without CaP (HX) are intended for cemented or cementless fixation.
The Humeral Fracture Stems and Proximal Bodies are intended for cemented or cementless fixation.
The Modular Stems 75mm are intended for cemented or cementless fixation.
The Modular Stems, fully corundum blasted, are intended for cementless fixation.
The Modular Stems, fully polished, are intended for cemented fixation.

Comparison to Predicate Device:

The subject modular humeral stem components are substantially equivalent to the predicate monoblock humeral stem components of the Embrace System in that they are used with the same Embrace Reverse Tray, Reverse Liner, Glenosphere, and Reverse Glenoid Baseplates and Screws for reverse total shoulder arthroplasty for the same indications. The subject modular humeral stems are manufactured from the same materials as the predicate Embrace system components, and are sterilized and packaged the same way.

The modularity of the subject humeral stem components is similar to the modularity found in the competitive predicate devices.

Performance Testing:

Non-clinical performance testing and analysis were provided, including:

- Range of Motion analysis (ASTM F1378)
- Fatigue testing with Fretting/Corrosion assessment and post-fatigue disassembly tests

The results of non-clinical performance testing demonstrate that the device is suitable for its intended purpose and Substantially Equivalent to the predicate or reference devices.

Clinical Testing:	Clinical performance testing was not required to demonstrate the substantial equivalence of this device.
Conclusion:	The subject LINK Embrace Shoulder System – Reverse Configuration is substantially equivalent to the predicate devices identified in this premarket notification.