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

February 5, 2021

Re: K200368
Trade/Device Name: LINK Embrace Total Shoulder System - Reverse Configuration
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, HSD, PAO
Dated: January 8, 2021
Received: January 8, 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,

Michael Owens
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)*
K200368

Device Name
LINK Embrace Shoulder System - Reverse Configuration

Indications for Use *(Describe)*
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 Baseplate 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 are intended for cemented or cementless 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:**
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**Date Prepared:** February 5, 2021

**Trade Name:** LINK Embrace Shoulder System – Reverse Configuration

**Common Name:** Artificial Shoulder Joint Replacement

**Regulation and Classification Name:**

21 CFR §888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis;

21 CFR §888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis

Product codes: PHX- Shoulder Prosthesis, Reverse Configuration;

HSD- Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented;

PAO- Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer + Additive, Cemented

**Predicate Devices:**

Primary Predicate:

Lima Corp. SMR Reverse Shoulder System: K110598

Additional Predicates:

Lima Corp. SMR Reverse Shoulder System: K100858, K101263

Biomet Corp. Comprehensive Reverse Shoulder System: K181611, K130390, K113069, K080642, K132239

**Device Description:**

Humeral Stems (Ti6Al4V) are available in monoblock designs, and feature a proximal modular taper connection for assembly to reverse tray components for rTSA configurations. The monoblock Humeral Stems are available in Standard Stems and Short Stems with a broad size spectrum, and in non-coated and Calcium Phospate coated versions. Humeral fracture stems are also available.

The Reverse Glenoid Baseplate (Ti6Al4V) hosts a central Bone Screw and up to 4 peripheral Bone Screws. The system includes anglestable (locking screws), polyaxial anglestable and standard screw fixation with cortical and cancellous thread designs. The baseplate's backside and central peg feature a porous titanium surface for biologic fixation. The Reverse Glenoid Baseplate is assembled with a CoCrMo Glenosphere for rTSA.

The LINK Embrace Shoulder System – Reverse Configuration offers Glenospheres in several diameters. And neutral and eccentric designs. The

Embrace Glenospheres are connected to the Reverse Baseplate by means of a taper and locking screw.

Reverse Trays (CoCrMo) are available in neutral, inclined and offset versions, which are combined with Reverse Inserts (polyethylene) in neutral and 10° & 20° inclined versions, enabling the surgeon to adjust the mechanical parameters in different spatial planes (e.g. retroversion and inclination) independently from each other. In addition, different Insert heights are available.

The reverse inserts are available in conventional polyethylene and in highly crosslinked polyethylene with Vitamin E (E-Dur®).

The LINK Embrace Shoulder System – Reverse Configuration is supported by a streamlined, lightweight and ergonomic instrument set.

**Intended Use:**

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 Baseplate 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.
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The Humeral Fracture Stems are intended for cemented or cementless fixation.

**Comparison to Predicate Device:**

The subject system is substantially equivalent to the predicates in that all are total shoulder systems intended for a reverse configuration, all describe use for primary, revision (i.e., previously failed joint replacement), or fracture indications, and all describe use for grossly rotator cuff deficient joints with severe arthropathy.

The predicate system is manufactured from Ti6Al4V alloy, CoCrMo alloy, and UHMWPE, like the predicates.

The subject and predicate systems include a range of humeral stems for cemented or cementless fixation within the humerus, which are assembled to trays with polyethylene liners that articulate with a metal glenosphere attached to a glenoid baseplate that is fixed to the glenoid with bone screws.

**Performance Testing:**

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

- Range of Motion analysis (ASTM F1378)
- Fatigue testing with Fretting/Corrosion assessment
- Glenoid baseplate loosening (ASTM F2028)
- Reverse Baseplate/Glenosphere Component Disassociation/Taper Connection Test (ASTM F2028)
- Reverse baseplate and insert disassembly (lever-out, push-out, torque-out) testing (ASTM F1820)

- Bone screw testing (ASTM F543)
- Wear rationale
- Impingement Testing (ASTM F2582)
- Characterization of UHMWPE sterilized by EO
- Characterization of TrabecuLink porous surfaces

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

**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.