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

June 21, 2021

Re: K210899
Trade/Device Name: LINK Embrace Shoulder System- Anatomical Configuration
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT, KWS, PAO, HSD
Dated: March 26, 2021
Received: March 29, 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 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)*
K210899

Device Name
LINK Embrace Shoulder System - Anatomical Configuration

Indications for Use *(Describe)*

General indications:

The LINK Embrace Shoulder System - Anatomic Configuration is intended for anatomic total or hemi shoulder arthroplasty.

Indications:

- A severely painful and/or disabled shoulder joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis
- Avascular necrosis of the humeral head
- Deformity and/or limited motion
- Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory
- Revision of a failed primary component
- Ununited humeral head fractures
- Cuff tear arthropathy (CTA Heads only)

The All Poly Glenoid Components are intended for cemented use.
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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(k) Number:	K210899
510(k) Submitter:	Waldemar Link GmbH & Co. KG Barkhausenweg 10 22339 Hamburg, Germany Phone: +49-40-539950 Facility Registration #:3003386935
Contact Person:	Waldemar Link GmbH & Co. KG Stefanie Fuchs *(Regulatory Affairs)* Oststraße 4-10 Norderstedt, GERMANY 22844 Phone: +49-40 53995-530 Fax: +49-40 53995-174 E-Mail: st.fuchs@linkhh.de
Date Prepared:	May 26, 2021
Trade Name:	LINK Embrace Shoulder System – Anatomical Configuration
Common Name:	Artificial Shoulder Joint Replacement
Classification Name:	Shoulder joint metal/polymer non-constrained cemented prosthesis; 21 CFR §888.3650, product code KWT Shoulder joint metal/polymer semi-constrained cemented prosthesis; 21 CFR §888.3660, product code KWS, PAO Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis; 21 CFR §888.3690, product code HSD
Classification and Panel:	Class II, Orthopedic / 87
Predicate Devices:	Lima Corp. SMR Shoulder System:: K161476 [Primary Predicate] Biomet Corp. Comprehensive Shoulder System:: K060692. LINK GmbH & Co KG: LINK Embrace Shoulder System – Reverse Configuration: K200368
Trade Name:	LINK Embrace Shoulder System – Anatomical Configuration
Device Description:	The LINK Embrace Shoulder System offers diverse fixation options suitable for the majority of patient populations and indications. A wide range of stems in different configurations allows for cemented and cementless fixation.

Humeral Stems (Ti6Al4V) are available in monoblock designs, and feature a proximal modular taper connection for assembly to head adapters. The monoblock Humeral Stems are available in Standard Stems and Short Stems with a broad size spectrum, and in non-coated and Calcium Phosphate coated versions. Humeral Fracture Stems are also available. The Humeral Stems have been previously cleared for use with the LINK Embrace Shoulder System – Reverse [K200368].

Humeral Heads (CoCrMo) are available in several sizes with a female taper for connection to the Head Adapters.

CTA Heads (CoCrMo) are available in neutral and different offset versions and feature a male taper for connection to Humeral Stems.

The Cemented All Poly Glenoids are available in conventional polyethylene and in highly crosslinked polyethylene with Vitamin E (E-Dur).

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

Indications for Use:

General indications: The LINK Embrace Shoulder System - Anatomic Configuration is intended for anatomic total or hemi shoulder arthroplasty.

Indications:

- A severely painful and/or disabled shoulder joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis
- Avascular necrosis of the humeral head
- Deformity and/or limited motion
- Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory
- Revision of a failed primary component
- Ununited humeral head fractures
- Cuff tear arthropathy (CTA Heads only)

The All Poly Glenoid Components are intended for cemented use.
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.

Comparison to the predicate: The subject system is substantially equivalent to the predicates in that all are hemi or total shoulder systems intended for an anatomic configuration, all describe use for primary, revision (i.e., previously

failed joint replacement), or fracture indications, and all describe use for cuff tear arthroplasty.

The subject system is manufactured from Ti6Al4V alloy with some components also having a CaP coating, 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 Humeral Heads (with corresponding Head Adapters) that articulate with Cemented All Poly Glenoids.

There are also minor differences between the subject and predicate systems. The subject and predicate Biomet systems include monolithic stems that mate with head adaptors and heads, while the predicate SMR system has modular stems that mate with humeral bodies, head adaptors and humeral heads. The subject CTA heads mate directly with the humeral stems, where the predicate LIMA CTA heads are used with an adapter. The subject All Poly Glenoids have 4 pegs and are available in conventional polyethylene and in highly crosslinked polyethylene with Vitamin E (E-Dur), whereas the predicate LIMA All Poly Glenoids have 3 pegs (or a single peg design) and are available in conventional polyethylene. The subject system offers head adaptors in several offsets and a neutral version with or without suture holes. The head adaptors are assembled to the humeral stems with a taper connection and assembly screw. The use of a supplemental assembly screw and the option for suture holes differs from the adapters of the predicate systems. All systems offer various component sizes to accommodate differences in patient anatomies, although the specific dimensions of each system's components are unique. All systems feature mechanical taper connections for assembly of the humeral constructs, although the specific dimensions of each system's tapers differ. Engineering analyses and mechanical tests were conducted to demonstrate equivalent performance despite minor design differences.

Performance Testing:

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

- Range of Motion analysis (ASTM F1378)
- Glenoid loosening (ASTM F2028)
- Fatigue testing with Fretting/Corrosion assessment
- Static and post-fatigue evaluation of component Locking Mechanisms (ASTM F2009)
- Wear Rationale
- Characterization of UHMWPE sterilized EO (reference K200368)
- Biocompatibility evaluation

	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 – Anatomical Configuration is substantially equivalent to the predicate devices identified in this premarket notification.