Waldemar Link GmbH & Co. KG
% Mateusz Leszczak
Regulatory Affairs Manager
LinkBio Corp.
69 King Street
Dover, New Jersey 07801

November 16, 2023

Re: K231445
Trade/Device Name: LINK Embrace 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, PAO
Dated: October 13, 2023
Received: October 13, 2023

Dear Mateusz Leszczak:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2023.11.16 12:35:14 -05'00'

for: Farzana Sharmin, PhD
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231445

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) are intended for cemented or cementless fixation.
The Humeral Fracture Stems and Proximal Bodies are intended for cemented or cementless fixation.
The Modular Stems 75 mm 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

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Date Prepared: November 16, 2023

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

Classification and Panel: Class II, Orthopedic / 87

Predicate Devices:

LINK Embrace Shoulder System – Reverse Configuration [Primary Predicate]	K200368
Stryker (Wright/Tornier) Aequalis PerFORM, PerFORM+	K161742
Zimmer Biomet Comprehensive Reverse Shoulder System	K080642 K120121 K172502
Arthrex Univers Revers Shoulder Prosthesis System	K130129 K142863

Reason for Submission:

Adds components to the predicate Embrace Total Shoulder System – Reverse Configuration: 25 mm diameter reverse glenoid baseplates (RGBs) in neutral, wedged, and lateralized designs with associated peripheral bone screws, a +5mm concentic reverse tray, and lateralized glenospheres.

Device Description:

This Line Extension portfolio includes:

- Smaller 25 mm Ø Reverse Glenoid Baseplates (RGBs) in neutral designs and in wedged (10°, 15° and 20°) and lateralized variants (+3mm and +6mm). The new 25mm Ø RGB components include new peripheral 4.5mm Ø cortical screws in lengths of 20-60mm with a reduced head diameter as compared with the predicate 4.5mm Ø cortical screws cleared in K200368. The screws are available in standard and angle-stable/locking versions.
- Glenospheres in sizes 36mm, 39mm and 42mm diameter with +3mm and +6mm lateralization.
- Humeral Reverse Tray in a neutral (concentric) version with extended +5mm height.

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) are intended for cemented or cementless fixation.
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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 Reverse Glenoid Baseplates differ from the primary predicate RGBs in that they are a smaller diameter (25 mm) and feature neutral baseplate designs with flat or convex backsides, as well as wedged and lateralized designs. These design features are similar to the secondary predicates.

The associated peripheral bone screws differ from their primary predicates with regard to the smaller screw head shape and anodization.

The Glenospheres differ from their primary predicates in that they offer options for lateralization. Lateralized glenospheres are also found in a secondary predicate system.

Except for the new design variations described above, which are similar to features in the secondary predicates, the subject line extension components are the same as their corresponding components of the previously cleared Embrace Total Shoulder System with regard to intended use, materials, manufacturing methods, packaging, and sterilization.

Performance Testing:

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

- Range of Motion analysis (ASTM F1378)
- Bone screw testing
- Wear testing rationale for no new worst case
- Glenoid fretting fatigue rationale for no new worst case
- Humeral fatigue test rationale for no new worst case
- Micromotion test (ASTM F2028)
- Biocompatibility Evaluation.

The results of non-clinical performance testing and evaluations 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.