February 20, 2025

LinkBio Corp.
Deniz Kortan
Sr. Quality Manager - Digital Surgery
69 King Street
Dover, New Jersey 07801

Re: K241470
Trade/Device Name: CORE Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: QHE, KWS, PHX
Dated: January 21, 2025
Received: January 21, 2025

Dear Deniz Kortan:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2025.02.20 14:03:17 -05'00'

Farzana Sharmin, Ph.D.
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.

510(k) Number *(if known)*
K241470

Device Name
CORE Shoulder System

Indications for Use *(Describe)*
The CORE Shoulder System is a handheld surgical instrument with computer-assisted instrument tracking and is intended to assist the surgeon with placement of the K-wire (central guide pin) used in the preparation of the glenoid and the positioning of the glenoid component during primary Anatomic or Reverse total shoulder arthroplasty. The CORE Shoulder System tracks the live position of the instruments relative to an untracked virtual anatomical model. It does not track the patient anatomy.
The CORE Shoulder System is designed for use with the following LINK Implant systems:
• LINK Embrace Shoulder System – Reverse Configuration (K200368, K212992, K231445)
• LINK Embrace Shoulder System – Anatomic Configuration (K210899)

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) Submitter:	LinkBio Corp. 69 King Street Dover, NJ 07801, USA Registration Number: 3006721341
Contact Person:	Deniz Kortan LinkBio Corp. 69 King Street Dover, NJ 07801, USA Phone: 1-800-932-0616 Email: d.kortan@linkbio.com
Date Prepared:	February 20, 2025
Trade Name:	CORE Shoulder System
Common Name:	Shoulder Arthroplasty Implantation System
Classification Name:	21 CFR §888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis QHE (Shoulder Arthroplasty Implantation System) KWS (Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented) PHX (Shoulder Prosthesis, Reverse Configuration)
Classification and Panel:	Class II, Orthopedic
Predicate Device:	Glenoid Intelligent Reusable Instrument System (Glenoid IRIS), by Cleveland Clinic, K123122 (Primary Predicate), and Virtual Implant Positioning (VIP) System, by Arthrex, K222007 (Additional Predicate).
Reason for Submission	New device
Device Description:	The CORE Shoulder System is a handheld surgical instrument with computer-assisted instrument tracking and is intended to assist the surgeon with placement of the K-wire (central guide pin) used in the preparation of the glenoid and the positioning of the glenoid component during primary Anatomic or Reverse total shoulder arthroplasty. CORE Shoulder assists the surgeon in placing the K-wire according to the preoperatively planned location. The CORE Shoulder System tracks the live

position of the instruments relative to an untracked virtual anatomical model. It does not track the patient anatomy.

It allows the surgeon to visually compare the planned and placed position/trajectory of the guide pin (K-wire) by referencing a virtual 3D model of the pre-operative plan and the measured location of the K-wire. The system components include the Workstation (tablet, AC adapter, stand), the handheld COREmote (single-use Power Unit and reusable Sensor Unit), and reusable stainless-steel probes of different sizes.

Indications for Use:

The CORE Shoulder System is a handheld surgical instrument with computer-assisted instrument tracking and is intended to assist the surgeon with placement of the K-wire (central guide pin) used in the preparation of the glenoid and the positioning of the glenoid component during primary Anatomic or Reverse total shoulder arthroplasty. The CORE Shoulder System tracks the live position of the instruments relative to an untracked virtual anatomical model. It does not track the patient anatomy.

The CORE Shoulder System is designed for use with the following LINK Implant systems:

- LINK Embrace Shoulder System – Reverse Configuration (K200368, K212992, K231445)
- LINK Embrace Shoulder System – Anatomic Configuration (K210899)

Comparison to Predicate Device:

The predicate device for the subject CORE Shoulder System is the Glenoid IRIS system.

Both the subject and predicate systems are intended to aid the surgeon in setting K-wire position (entry point and orientation) according to a patient-specific pre-operative plan for the intended glenoid implant position.

Both the predicate and subject devices rely on pre-operative planning software that uses CT data to create a virtual model of the patient's scapula and determine the K-wire position associated with the desired implant position. The predicate Glenoid IRIS uses its own proprietary software for pre-operative planning, while the CORE Shoulder uses a commercially available software legally marketed for this purpose (K170702).

Both systems assist the surgeon in visually comparing the planned and placed K-wire position by referencing a 3D model of the pre-operative plan. In the case of the predicate device, the 3D model is a physical model, and in the case of the subject CORE Shoulder device, the 3D model is a virtual model. The CORE Shoulder also provides computer-assisted instrument tracking to help target the K-wire by tracking the position of the instrument relative to an untracked virtual model. The CORE Shoulder device interacts wirelessly with the computer tablet running the CORE software to display this information. This is a technological difference from the predicate Glenoid IRIS which does not provide computer-assisted instrument tracking.

The subject and predicate devices both feature reusable Stainless Steel components for contact with the glenoid which include a guide for drilling the K-wires.

Both the subject and predicate devices have the same intended purpose. There are some differences in technological characteristics, but both systems provide a method for comparing the planned and placed K-wire position compared to the pre-operative plan, and scientific methods exist for evaluating the effect of the different technological characteristics on safety and effectiveness. The performance testing provided supports the Substantial Equivalence of the subject device for its intended purpose.

Performance Testing:

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

- Battery Life
- Sensor Unit Lifecycle
- Patient Motion Risk Assessment
- Comparative testing of K-wire placement versus pre-op plan in analogue glenoid models
- Cadaver testing comparing both K-wire placement and implant position versus pre-op plan
- Accuracy testing for K-wire Placement Check feature
- Usability evaluation
- Biocompatibility Evaluation per ISO 10993-1
- Electrical safety testing per IEC 60601-1
- EMC testing
- Cybersecurity Evaluation
- Software validation testing
- Sterilization validation testing

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.

Clinical Testing:

Clinical performance testing was not required to demonstrate the substantial equivalence of this device.

Conclusion:

The subject device is substantially equivalent to the predicate device identified in this premarket notification.