LimaCorporate S.p.A.
% Kenneth Newman
Regulatory Affairs Associate
Lima USA Inc.
2001 NE Green Oaks Blvd. Ste. 100
Arlington, Texas 76006

October 26, 2022

Re: K222807
Trade/Device Name: TEMA Elbow system - Line extension
Regulation Number: 21 CFR 888.3160
Regulation Name: Elbow joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDB, JDC
Dated: August 30, 2022
Received: September 16, 2022

Dear Kenneth Newman:

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,

Victoria Lilling, M.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)*
K222807

Device Name
TEMA Elbow system – Line extension

Indications for Use *(Describe)*

TEMA Elbow system is intended for use in cemented applications for patients suffering from disability due to:

1. Elbow joint destruction which significantly compromises the activities of daily living
2. Non-Inflammatory degenerative joint disease including osteoarthritis, and avascular necrosis with hemophilia.
3. Rheumatoid arthritis or degenerative arthritis with incapacitating pain
4. Revision where other devices or treatments have failed.
5. Correction of severe functional deformity.
6. Treatment of acute or chronic fractures with distal humerus epicondyle involvement.
7. Post-traumatic lesions or bone loss contributing to elbow instability or loss of motion

The unlinked, semi-constrained version is for use in cases where there are functioning medial and lateral elbow ligaments of good quality that provide immediate stability, resisting any tendency of dislocation or disengagement between ulnar and humeral components, when intraoperative manual testing is performed.

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

Date: October 21, 2022

Manufacturer:
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Product	Product Code	Regulation and Classification Name
TEMA Elbow System – Line extension	JDC	21 CFR 888.3150 Elbow joint metal/polymer constrained cemented prosthesis
	JDB	21 CFR 888.3160 Elbow joint metal/polymer semi-constrained cemented prosthesis

Description:

TEMA Elbow System is a cemented total elbow prosthesis. The system provides both linked (constrained) and unlinked (semi-constrained) configurations.

TEMA Elbow System consists of modular humeral and ulnar assemblies. The humeral assembly consists of a metallic humeral stem and a metallic humeral body component with pre-assembled polyethylene bushings. The ulnar assembly is composed of a metallic ulnar stem, a metallic ulnar body and a polyethylene ulnar liner. Screws are used to secure the taper couplings between the stems and bodies of the humeral and ulnar assemblies.

The constrained (linked) version of the elbow consists of the modular humeral assembly and the modular ulnar assembly with an axle component that is inserted across the joint to connect the humeral assembly to the ulnar assembly.

The semi-constrained (unlinked) version consists of the same components without the use of the axle to link the humeral and ulnar assemblies.

TEMA Elbow system – Line extension introduces two new sizes of Ulnar stems to the ulnar stem range already cleared; moreover, a design change is introduced for the axle component, ulnar body component and for the humeral body compared to the original cleared version.

Indication for Use:

TEMA Elbow system is intended for use in cemented applications for patients suffering from disability due to:

1. Elbow joint destruction which significantly compromises the activities of daily living
2. Non-Inflammatory degenerative joint disease including osteoarthritis, and avascular necrosis with hemophilia.
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Predicate Devices:

Company	Device name	Cleared via
LIMACORPORATE	TEMA Elbow system	K181362

Summary of technology comparison:

TEMA Elbow system – line extension and TEMA Elbow system (predicate device) have extensive and significant similarities in terms of intended use, indications, technological characteristics, materials, and principles of operation. The differences between these two systems are related to a design improvement of axle, humeral body and ulnar body components aimed to improve the overall mechanical performance and laxity of the system plus the addition of two new sizes of Ulnar stems.

A comparison of technological characteristics and performance testing demonstrate that the TEMA Elbow system-line extension is substantially equivalent to the predicate devices.

Non-clinical testing

Mechanical evaluations (both bench tests and rationales) demonstrated the device's ability to perform in a substantially equivalent manner to the predicate devices in terms of:

- Range of motion;
- Stability, fatigue and fretting-corrosion evaluation post-fatigue of modular connections;
- Wear evaluation.

Clinical testing
Clinical testing was not necessary to demonstrate substantial equivalence of the TEMA Elbow system – Line extension components to the predicate device.

Conclusion
Based upon a comparison of intended use, materials, summary of technological characteristics, and preclinical testing, the TEMA Elbow system – Line extension components are substantially equivalent to the predicate device components identified in this premarket notification.