February 16, 2019

Limacorporate S.p.A.
% Stephen Peoples
President
Peoples & Associates Consulting LLC
5010 Lodge Pole Lane
Fort Wayne, Indiana 46814

Re: K181362
Trade/Device Name: TEMA Elbow System
Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow Joint Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDC, JDB
Dated: January 28, 2019
Received: January 30, 2019

Dear Stephen Peoples:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqi -S

Digitally signed by Vesa Vuniqi -S
Date: 2019.02.16 20:05:07 -05'00'

For: Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K181362

Device Name
TEMA Elbow System

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 intended 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 of Safety and Effectiveness

Date Prepared: May 15, 2018
Manufacturer: Limacorporate
S.p.A. Via Nazionale, 52
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U.S. Contact Person: Dr.
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Product	Common Name	Product Code	Regulation and Classification Name
TEMA Elbow System	Total Elbow Prosthesis	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.
All of the system components are available in different sizes.
The modularity of the polyethylene ulnar component also allows replacement of the ulnar bearing, if needed, without removal of the humeral and ulnar assemblies. The modularity also provides an additional advantage that if replacement of the humeral and/or ulnar body is needed (e.g. due to damage from a traumatic event or due to excessive wear of the bushing of the humeral body) and the stem components are well fixed, the stems do not need to be removed and only disconnection of the humeral and ulnar bodies from the stems is required for their revision.

Indications 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.
3. Rheumatoid arthritis or degenerative arthritis with incapacitating pain
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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.

Predicate Devices:

The following predicate devices for Limacorporate TEMA Elbow System:

- Conrad Morrey Total Elbow (Zimmer Inc., K001989 / K053189);
- Latitude Elbow Prosthesis (Tornier Inc., K100562 / K171010);
- Solar Elbow Prosthesis (Howmedica Osteonics Corp aka Stryker Corporation, K980502);
- Discovery Elbow (Biomet Inc., K013042 / K051975 / K090473);
- Nexel Total Elbow (Zimmer Inc., K123862).

Reference Devices:

- K100858 – SMR Shoulder System
- K133349 – SMR TT Metal Back Glenoid

Technological Characteristics to the Predicate Device(s):

The TEMA Elbow System has the same intended use, similar design and materials to the predicate devices. All of the systems feature humeral and ulnar components with articulating bushings at the joint. The TEMA Elbow System consists of modular assemblies to allow the replacement of the ulnar bearing, if needed, without removal of the humeral and ulnar assemblies. The modularity also provides an additional advantage that if replacement of the humeral and/or ulnar body is needed (e.g. due to damage from a traumatic event or due to excessive wear of the bushing of the humeral body) and the stem components are well fixed, the stems do not need to be removed. Only the disconnection of the humeral and ulnar bodies from the stems is required for their revision.

Non-Clinical Testing:

Mechanical testing demonstrated the device's ability to perform in a substantially equivalent manner to the predicate devices in terms of:

- Range of motion;
- Fatigue testing of humeral stem;
- Fatigue testing of ulnar stem;
- Stability, fatigue, and corrosion testing of modular connections;
- Wear testing.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of TEMA Elbow System to the predicate devices.

Conclusions

The intended use, design, and materials of TEMA Elbow System are substantially equivalent to the intended use, design and materials of the predicate devices. Design Control analyses and testing indicate that no new issues regarding safety and effectiveness are raised by the design, materials or intended use of the Lima Elbow System.