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

October 6, 2022

Re: K222427
Trade/Device Name: PRIMA TT Glenoid
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBF, PHX
Dated: August 8, 2022
Received: August 11, 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,

For 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)*
K222427

Device Name
PRIMA TT Glenoid

Indications for Use *(Describe)*

The PRIMA Glenoid System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy (disabled shoulder). The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.
The PRIMA Glenoid System components are intended for uncemented use with the addition of screw fixation.

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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.

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Department of Health and Human Services
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"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

Date: October 06, 2022

Manufacturer:
LimaCorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

U.S. Contact Person:
Kenneth Newman
Kenneth.Newman@limacorporate.com
Lima USA Inc.
2001 NE Green Oaks Blvd. Ste.100
Arlington, Texas 76006, USA
www.limacorporate.com
Cell Phone: 682-597-3381

Product	Product Code	Regulation and Classification Name
PRIMA TT Glenoid	MBF	21 CFR 888.3670 – Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis
	PHX	21 CFR 888.3660 – Shoulder joint metal/polymer semi-constrained cemented prosthesis

Description

The PRIMA TT Glenoid, that is part of the PRIMA Glenoid System, is a modular shoulder system intended to be used in combination with the previously cleared humeral components of the SMR Shoulder System (K220792) and PRIMA Humeral System (K212800).

The new system components include a monoblock glenoid baseplate, a modular glenoid baseplate and the related glenoid peg, a glenosphere, a glenosphere connector with screw, central and peripheral bone screws and locking caps.

The baseplates are provided in different angulations, ranging between 10° and 20°, and in different offsets, up to +4mm lateralization. The glenosphere has articular diameter 36, 40 and 42mm and the connector with screw is available in low, medium and high lateralization. Central compressive screws are available in dia. 5 and 6.5mm and in length ranging between 25 and 50mm, while peripheral screws are available in dia. 5mm and in length ranging between 18 to 50mm.

Baseplates, peg, screws and locking cap are made of Ti6Al4V, the glenosphere is made of CoCrMo and the glenosphere connector with screw is made of Ti6Al4V and UHMWPE.

Indications for Use

The PRIMA Glenoid System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy (disabled shoulder). The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The PRIMA Glenoid System components are intended for uncemented use with the addition of screw fixation.

Predicate Devices:

No.	Company	Device name	Cleared via
1 (Primary Predicate)	LimaCorporate S.p.A	SMR Reverse Liner	K220792
2	Tornier, Inc.	Aequalis PerFORM Reversed, Aequalis PerFORM+ Reversed Glenoid	K161742

Summary of technology comparison

PRIMA TT Glenoid and SMR Shoulder System including SMR TT Augmented 360 Glenoid (primary predicate) have extensive and significant similarities in terms of intended use, indications, technological characteristics, materials, and principles of operation. The main differences between these two systems relates to the presence of porous surface on the backside of the baseplates and the use of the central compressive screw, features that are not available for the predicate device. To establish a proper and complete substantial equivalence discussion of the subject device with marketed predicate devices, the Aequalis PerFORM & Aequalis PerFORM+ Reversed Glenoids is also included as predicate devices for PRIMA TT Glenoid. The predicate Aequalis PerFORM & Aequalis PerFORM+ Reversed Glenoids features a porous surface on the backside of the baseplates and the use of the central compressive screw.

A comparison of technological characteristics and performance testing demonstrate that the PRIMA TT Glenoid is substantially equivalent to the predicate devices.

Non-clinical testing

Mechanical tests demonstrated that device performance fulfilled the intended use and that the devices is substantially equivalent to the predicate devices.

Mechanical testing was performed on worst case components or constructs:

- Evaluation of modular connection dissociation strength
- Fatigue fretting test on glenoid baseplates in reverse shoulder configuration
- Evaluation of modular connection dissociation strength post-fatigue
- Dynamic Evaluation of the Glenoid Loosening or Disassociation (ASTM F2028)
- Evaluation of range of motion for worst case devices

Clinical testing

Clinical testing was not necessary to demonstrate substantial equivalence of PRIMA TT Glenoid to the predicate devices.

Conclusion

Based upon a comparison of intended use, materials, summary of technological characteristics, and preclinical testing, PRIMA TT Glenoid is substantially equivalent to the predicate devices identified in this premarket notification.