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

January 11, 2024

Re: K233712
Trade/Device Name: PRIMA Humeral System; 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, HSD, PAO, KWS, KWT
Dated: November 14, 2023
Received: November 20, 2023

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 (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,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2024.01.11 17:42:36 -05'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K233712

Device Name

PRIMA Humeral System

Indications for Use *(Describe)*

The PRIMA Humeral System is intended for partial or total, primary or revision, shoulder joint replacement in skeletally mature patients. 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 Short Stem and PRIMA Short Stem Plus are intended for use in cementless and cemented applications, at the discretion of the surgeon.

The PRIMA Anatomic implant is indicated for partial or total, primary or revision shoulder joint replacement, in patients suffering from pain and disability due to:

- Non-inflammatory degenerative joint disease (i.e. osteoarthritis),
- Inflammatory arthritis of the glenohumeral join including rheumatoid arthritis,
- Avascular necrosis of the humeral head,
- Traumatic/post-traumatic arthritis,
- Fractures of the humeral head where adequate fixation can be achieved and adequate bone stock remains,
- Post-fracture deformity with intact rotator cuff, where adequate fixation can be achieved and adequate bone stock remains,
- Cuff tear arthropathy (CTA Heads only).

The PRIMA Reverse implant is indicated for primary reverse total shoulder replacement or for revision when converting an anatomic PRIMA arthroplasty to a reverse total shoulder arthroplasty (i.e. in case of cuff tear arthropathy or in a grossly rotator cuff deficiency joint with severe arthropathy).
Revision surgery with retention of the PRIMA Short Stem and PRIMA Short Stem Plus are intended as conversion surgery from anatomic to reverse, where the stem is stable, well positioned and tissue integrated. Other revisions of the humeral prosthesis part should be treated with traditional shoulder prostheses.

The PRIMA reverse implant is indicated for patients suffering from pain and disability due to:

- Rotator cuff tear arthropathy,
- Osteoarthritis with rotator cuff tear,
- Rheumatoid arthritis with rotator cuff tear,
- Massive irreparable rotator cuff tear,
- Avascular necrosis of the humeral head,
- Correction of functional deformity, where adequate fixation can be achieved and adequate bone stock remains,

- Fractures of the humeral head where adequate fixation can be achieved and adequate bone stock remains.

The PRIMA Humeral System consists of the following single use components:

- Anatomic configuration:
  - stem
  - adaptor for humeral heads.
- Reverse configuration:
  - stem
  - reverse tray
  - reverse insert.

System		Components	Material
A	R		
•	•	PRIMA Short Stem	Ti6Al4V 3d printed
•	•	PRIMA Short Stem Plus	Ti6Al4V 3d printed
•		ADAPTOR FOR HUMERAL HEADS	Ti6Al4V
	•	REVERSE TRAY	Ti6Al4V
	•	REVERSE INSERT	LimaVit™ (Vitamin E highly crosslinked UHMWPE), Ti6Al4V
Material Standards Ti6Al4V (ISO 5832-3 - ASTM F1472), Ti6Al4V 3d printed (ISO 5832-3), LimaVit™ (Vitamin E highly crosslinked UHMWPE) (ISO 5834-2 - ASTM F648 - ASTM F2695 – ASTM F2565)			
A = Anatomic, R = Reverse			

Table 1 PRIMA Humeral System components materials

The PRIMA Humeral System is intended to be used with all glenoids implants belonging to the SMR Shoulder System and PRIMA Glenoid System.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233712

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.

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.

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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: January 02, 2024

Manufacturer:
LimaCorporate S.p.A.
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Product	Product Code	Regulation and Classification Name
PRIMA Humeral System	HSD	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented per 21 CFR 888.3690
	PAO	Shoulder joint metal/polymer semi-constrained cemented prosthesis, per 21 CFR 888.3660
	PHX	Shoulder Prosthesis, Reverse Configuration per 21 CFR 888.3660
	KWS	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented per 21 CFR 888.3660
	KWT	Prosthesis, Shoulder, Non-Constrained, Metal/Polymer Cemented per 21 CFR 888.3650
PRIMA TT Glenoid	MBF	Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3670
	PHX	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Common name:

Product	Common name
PRIMA Humeral System including PRIMA Short Stem Plus	Humeral shoulder prosthesis
PRIMA TT Glenoid including Central Compressive Cortical and Cancellous Screws L 20mm	Glenoid shoulder prosthesis

Description:

This 510(k) submission aims at introducing new components to the previously cleared PRIMA Humeral (K212800) and Glenoid (K222427) systems.

The PRIMA Short Stem Plus is introduced as part of the PRIMA Humeral System. As the already cleared PRIMA Short Stem, the PRIMA Short Stem Plus is a convertible short stem component with proximal (metaphyseal) fixation with Trabecular Titanium to be used in both anatomic and reverse configurations. Depending on the configuration, the

stem component can be coupled with an Adaptor for the humeral heads for the anatomic configuration and with a Reverse Tray and Reverse Insert in reverse configuration.
The PRIMA Short Stem Plus is intended for use in cementless and cemented applications.
The PRIMA Short Stem Plus is made of Ti6Al4V (ISO 5832-3) and is available in two different lengths: 86 mm and 96 mm. Each length is available in seven different sizes, varying from 28mm to 40mm in the proximal diameter.

The PRIMA TT Glenoid Central Compressive Cortical and Cancellous Screws in length 20mm are introduced as part of the PRIMA Glenoid System, as an additional option to the already available sizes (length 25 to 50mm), cleared via K222427. The PRIMA TT Glenoid Central Compressive Cortical and Cancellous Screws are intended to be inserted in the central hole of the glenoid baseplate and are used to fix the PRIMA TT Glenoid baseplates to the glenoid bone.
As for the already cleared central compressive screws of PRIMA TT Glenoid, the PRIMA TT Glenoid Central Compressive Cortical and Cancellous Screws in length 20 mm are manufactured from Ti6Al4V (ASTM F1472, ISO 5832-3) and have respectively diameter 5mm (cortical) and 6.5mm (cancellous).

Indications for Use:

PRIMA Humeral System

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The PRIMA Anatomic implant is indicated for partial or total, primary or revision shoulder joint replacement, in patients suffering from pain and disability due to:

- Non-inflammatory degenerative joint disease (i.e. osteoarthritis),
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The PRIMA reverse implant is indicated for patients suffering from pain and disability due to:

- Rotator cuff tear arthropathy,
- Osteoarthritis with rotator cuff tear,
- Rheumatoid arthritis with rotator cuff tear,
- Massive irreparable rotator cuff tear,
- Avascular necrosis of the humeral head,

- Correction of functional deformity, where adequate fixation can be achieved and adequate bone stock remains,
- Fractures of the humeral head where adequate fixation can be achieved and adequate bone stock remains.

The PRIMA Humeral System consists of the following single use components:

- Anatomic configuration:
  - stem
  - adaptor for humeral heads.
- Reverse configuration:
  - stem
  - reverse tray
  - reverse insert.

System		Components	Material
A	R		
•	•	PRIMA Short Stem	Ti6Al4V 3d printed
•	•	PRIMA Short Stem Plus	Ti6Al4V 3d printed
•		Adaptor for humeral heads	Ti6Al4V
	•	Reverse tray	Ti6Al4V
	•	Reverse insert	LimaVit™ (Vitamin E highly crosslinked UHMWPE), Ti6Al4V
Material Standards Ti6Al4V (ISO 5832-3 - ASTM F1472), Ti6Al4V 3d printed (ISO 5832-3), LimaVit™ (Vitamin E highly crosslinked UHMWPE) (ISO 5834-2 - ASTM F648 - ASTM F2695 – ASTM F2565)			
A = Anatomic, R = Reverse			

Table 1 PRIMA Humeral System components materials

The PRIMA Humeral System is intended to be used with all glenoids implants belonging to the SMR Shoulder System and PRIMA Glenoid System.

PRIMA TT Glenoid

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	PRIMA TT Glenoid	K222427
2	LimaCorporate S.p.A	PRIMA Humeral System	K212800
3	DJO	Altivate Shoulder Prostheses Stem	K172351

Summary of technology comparison:

The intended use, design, and materials of the PRIMA Humeral System and PRIMA TT Glenoid are substantially equivalent to the ones of the predicate devices.

Non-clinical testing

Mechanical tests demonstrated that device performance fulfilled the intended use and that

the devices are substantially equivalent to the predicate devices.
Mechanical testing was performed on worst case components or constructs:

- Fatigue test of the humeral stem
- Dynamic Evaluation of the Glenoid Loosening or Disassociation (ASTM F2028)

Clinical testing

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

Conclusion

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