July 11, 2023

LimaCorporate S.p.A.
Kenneth Newman
Senior Regulatory Affairs Specialist
Via Nazionale, 52
Villanova di San Daniele del Friuli, Udine 33038
Italy

Re: K231925
Trade/Device Name: MINIMA S System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, JDI, KWY, KWZ, LPH, MBL
Dated: June 27, 2023
Received: June 30, 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 (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,

Limin Sun -S

Limin Sun, 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231925

Device Name

MINIMA S System

Indications for Use *(Describe)*

The MINIMA S System stems are indicated for use in partial or total hip arthroplasty and are intended for press-fit (uncemented) use. When used in total hip arthroplasty, the MINIMA S Stems are intended for use with compatible femoral heads and acetabular components. When used in partial hip arthroplasty, the MINIMA S stems are intended for use with Lock Bipolar Heads.
Hip arthroplasty is intended for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis and hip dysplasia;
- rheumatoid arthritis;
- treatment of femoral head and neck fracture;
- revisions in cases of good remaining femoral bone stock.

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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5. 510(K) SUMMARY

Device Trade Name:	MINIMA S System
Manufacturer:	LimaCorporate S.p.A. Via Nazionale, 52 33038 Villanova di San Daniele del Friuli Udine, Italy
Contact:	Kenneth Newman Senior Regulatory Affairs Specialist Phone: +1 682-597-3391 Email: kenneth.newman@limacorporate.com
Date Prepared:	June 27, 2023
Classification:	21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. 21 CFR 888.3550 Hip joint metal/polymer semi-constrained cemented prosthesis. 21 CFR 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis. 21 CFR 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis. 21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Class:	II
Product Code:	LZO, KWY, KWZ, LPH, MBL
Predicate Devices:	Primary predicate: MINIMA S System (LimaCorporate, K141327) Additional predicate: SMS Cementless Stem (Medacta International SA, K201673)

Indications for Use:

The MINIMA S System stems are indicated for use in partial or total hip arthroplasty and are intended for press-fit (uncemented) use. When used in total hip arthroplasty, the MINIMA S Stems are intended for use with compatible femoral heads and acetabular components. When used in partial hip arthroplasty, the MINIMA S stems are intended for use with Lock Bipolar Heads.

Hip arthroplasty is intended for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis and hip dysplasia;
- rheumatoid arthritis;
- treatment of femoral head and neck fractures;
- revisions in cases of good remaining femoral bone stock.

Device Description:

The MINIMA S System is intended for partial or total hip arthroplasty in cementless use. It is a monolithic collarless stem currently available in 9 sizes (sizes from 4 to 12) in standard and lateralized versions. This Special 510(k) is to introduce Size 3 of the stem. Also this size comes in a standard and a lateralized version.

The Minima S stem is made of Ti6Al4V, and it has a plasma sprayed titanium coating in the proximal area (ASTM F1472, ISO 5832-3). The stem is characterized by a 12/14 conical taper to be coupled to LimaCorporate Femoral Heads, Biolox Delta femoral heads or Lock Bipolar Heads.

Substantial Equivalence:

MINIMA S #3 has identical indications for use, manufacturing steps, materials, fundamental technology and overall design of the other stems belonging to the MINIMA S System, sizes 4 to 12, cleared through K141327.

The MINIMA S #3 stem has a length comparable with the shortest sizes of the SMS Cementless Stem (Medacta International SA, K201673).

Preclinical Testing:

The stem MINIMA S #3 does not represent a worst case for mechanical testing. Test results of the stems already cleared through K141327 are applicable. Additional testing to demonstrate substantial equivalence to predicate devices is thus not required.

Clinical Testing:

Clinical testing was not necessary to support equivalence.

Conclusion:

The MINIMA S #3 stem possesses the same intended use and technological characteristics as the predicate devices. Therefore, MINIMA S #3 is substantially equivalent for its intended use.