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

December 20, 2022

Re: K222405
Trade/Device Name: Smart SPACE Shoulder Planner and 3D Positioners
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: QHE, KWS, MBF
Dated: November 18, 2022
Received: November 21, 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,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2022.12.20 13:50:10 -05'00'

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)*

K222405

Device Name

Smart SPACE Shoulder Planner and 3D Positioners

Indications for Use *(Describe)*

Smart SPACE Shoulder 3D Positioners and Anatomical Models

The Smart SPACE Shoulder 3D Positioners and Anatomical Models are intended to be used as surgical instruments for adult patients that are candidates for primary elective shoulder replacement surgery and they are intended to be a surgical tool to transfer a pre-operative plan into surgery, designed on the basis of patient-specific pre-operative CT scans.

The Smart SPACE Shoulder 3D Positioners are intended, by guiding the surgical instruments in some steps of the orthopedic surgical procedure, to prepare the bone to host the implantable components.

The Smart SPACE Shoulder Anatomical Models are a 3D representation of the patient anatomical condition, as previously evaluated by the surgeon. The model is intended to be used to check that the 3D Positioner(s) is properly placed on the anatomical compartment.

These devices must be exclusively utilized by an orthopedic surgeon who has a good knowledge of the specific operative technique.

Smart SPACE Shoulder 3D Positioners and Anatomical Models are indicated for use on adult patients that are candidates for primary elective reverse and anatomic total shoulder arthroplasty.

Smart SPACE Shoulder Planner

Smart SPACE Shoulder Planner is a medical device for surgeons composed of one software component. It is intended to be used as a pre-surgical planner for shoulder orthopedic surgery.

Smart SPACE Shoulder Planner does not include any system to manufacture the shoulder patient-specific instrumentation.

Smart SPACE Shoulder Planner is intended to be used by an orthopedic surgeon, with clinical experience in shoulder replacement surgery to make decisions regarding implant position, orientation and sizing.

Smart SPACE Shoulder Planner is intended to be used for adult patients planning only. The Smart SPACE Shoulder Planner is intended for use with patients that are candidates for primary reverse and anatomic total shoulder arthroplasty.

The specific functionalities of the Smart SPACE Shoulder Planner version are described in the User Manual and Quick Start Guide provided by LimaCorporate.

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: December 20th, 2022

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

U.S. Contact Person:
Dr. 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

Trade name: Smart SPACE Shoulder Planner and 3D Positioners.
Common Name: Shoulder Arthroplasty Implantation System

Classification Name:

Product Code	Regulation and Classification Name
QHE	Shoulder Arthroplasty Implantation System per 21 CFR 888.3660
KWS	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented per 21 CFR 888.3660
MBF	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer, Uncemented per 21 CFR 888.3670

Description:
The Smart SPACE Shoulder Planner consists of a software which assists the user in planning anatomic total or reverse shoulder arthroplasty. It provides the user to select surgical execution using either a glenoid 3D positioner or *Smart SPACE Shoulder Cubit Guidance.*
The Smart SPACE Shoulder system was cleared by TechMah Medical via K202151, K202454, K191247, and it includes the Smart SPACE Shoulder Planner, the Cubit Guidance system, the 3D Humeral and Glenoid Positioners and the Anatomical models.
TechMah Medical became part of Limacorporate S.p.A in 2021.
With this registration, LimaCorporate aims to:

- introduce an upgrade of the Smart SPACE Shoulder Planner;
- introduce the Smart SPACE Shoulder 3D Positioners and Anatomical Models manufactured by LimaCorporate, that are provided non-sterile.

Indications for Use:

Smart SPACE Shoulder 3D Positioners and Anatomical Models
The Smart SPACE Shoulder 3D Positioners and Smart SPACE Shoulder Anatomical Models are intended to be used as surgical instruments for adult patients that are candidates for primary elective shoulder replacement surgery and they are intended to be a surgical tool to transfer a pre-operative plan into surgery, designed on the basis of

patient-specific pre-operative CT scans.

The Smart SPACE Shoulder 3D Positioners are intended, by guiding the surgical instruments in some steps of the orthopedic surgical procedure, to prepare the bone to host the implantable components.

The Smart SPACE Shoulder Anatomical Models are a 3D representation of the patient anatomical condition, as previously evaluated by the surgeon. The model is intended to be used to check that the 3D Positioners is properly placed on the anatomical compartment.

These devices must be exclusively utilized by an orthopaedic surgeon who has a good knowledge of the specific operative technique.

Smart SPACE Shoulder 3D Positioners and Anatomical Models are indicated for use on adult patients that are candidates for primary elective reverse and anatomic total shoulder arthroplasty.

Smart SPACE Shoulder Planner

Smart SPACE Shoulder Planner is a medical device for surgeons composed of one software component. It is intended to be used as a pre-surgical planner for shoulder orthopedic surgery.

Smart SPACE Shoulder Planner does not include any system to manufacture the shoulder patient-specific instrumentation.

Smart SPACE Shoulder Planner is to be used for adult patients only and should not be used for diagnostic purposes.

Smart SPACE Shoulder Planner is intended to be used for adult patients planning only. The Smart SPACE Shoulder Planner is intended for use with patients that are candidates for primary reverse and anatomic total shoulder arthroplasty.

The specific functionalities of the Smart SPACE Shoulder Planner version are described in the User Manual and Quick Start Guide provided by LimaCorporate.

Predicate Devices:

No.	Company	Device name	Cleared via
1	TECHMAH MEDICAL LLC	Smart SPACE Shoulder System	K202151, K202454, K191247,

Summary of technology comparison:

The Smart SPACE Shoulder Planner and 3D Positioners manufactured by LimaCorporate S.p.A. and the *Smart SPACE Shoulder System (K202151*) manufactured by *TechMah Medical LLC* have substantially equivalent principles of operation and performance characteristics, with the exception of minor differences that aims to improve the software speed and memory usage, improve the user experience and solve bugs.

The Smart SPACE Shoulder 3D Positioners manufactured by LimaCorporate S.p.A. and the *Smart SPACE 3D Positioners (K202151*) manufactured by *TechMah Medical LLC* have substantially equivalent principles of operation, materials and performance characteristics.
The Smart SPACE Shoulder Glenoid 3D Positioners of the subject device are characterized by three similar designs that differ in minor design characteristics and are equivalent to the predicate device *K202151*. The Smart SPACE Shoulder Humerus 3D Positioner is provided with the same design of the device *K202151*.

Non-clinical testing
The Software Testing has been performed on Smart SPACE Shoulder Planner according to the requirements of ANSI AAMI IEC 62304:2006/A1:2015.

Clinical testing
Clinical testing was not necessary to demonstrate substantial equivalence of the subject devices to the predicate devices.

Conclusion
Based upon a comparison of intended use, materials, summary of technological characteristics, and preclinical testing, the Smart SPACE Shoulder Planner and 3D Positioners manufactured by LimaCorporate S.p.A are substantially equivalent to the predicate device identified in this premarket notification.