LAP GmbH Laser Applikationen
℅ Sebastian Boldhaus
Regulatory Affairs Manager
Zeppelinstraße 23
Lüneburg, 21337
GERMANY

March 29, 2024

Re: K232031
Trade/Device Name: Luna 3D
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: July 6, 2023
Received: July 7, 2023

Dear Sebastian Boldhaus:

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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
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)*

K232031

Device Name

LUNA 3D

Indications for Use *(Describe)*

The LAP LUNA 3D system is used to support reproducible patient positioning and monitor patient surface motion during radiotherapy and radiosurgery treatments and during CT simulation for radiation therapy planning. LAP LUNA 3D may also be used to guide patients through breath-holds. The LAP LUNA 3D system can be used for all patients, undergoing radiotherapy and radiosurgery treatments and CT simulation for radiation therapy planning.

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.

510(k) Summary of Safety and Effectiveness

In accordance with the requirements of the Safe Medical Device Act, LAP GmbH Laser Applikationen herewith submits a Summary of Safety and Effectiveness.
This 510(k) summary for the LUNA 3D meets the requirements of 21 CFR 807.92.

Submitter information: LAP GmbH Laser Applikationen
Zeppelinstrasse 23
21337 Lueneburg
Phone: +49 4131 951167
Fax: +49 4131 951196

Establishment Registration Number: 9681134
Owner/Operator Number: 9019434

Official Correspondent: Sebastian Boldhaus
Zeppelinstrasse 23
21337 Lueneburg
Germany
Phone: +49 4131 9511357
Email: s.boldhaus@lap-laser.com

US Agent (Contact): Trent Van Arkel
LAP of America Laser Applications, L.C.
161 Commerce Rd Ste 3
Boynton Beach, FL 33426
Phone: 561 4169250
Fax: 561 4169263
Email: Tava@Lap-Laser.com

Date Prepared: 28th of March 2024

Device(s) Identification:

Device trade name:	LUNA 3D
Common name:	Surface Guided Radio Therapy System (Patient Positioning System – accessory to a linear accelerator)

Classification of the device:

Device Classification Name:	Medical charged-particle radiation therapy system
Product Code:	IYE
C.F.R. Section.:	892.5050
Classification Panel:	Radiology devices
Device Class:	Class II

Device Description:

The LUNA 3D optical camera system captures the current 3D patient skin surface with one or multiple camera pods. The software calculates the spacial deviations between the captured live surface and a reference surface within a selected region of interest using a registration algorithm. Reference surfaces may be generated with the optical camera system or may be imported using data received from Treatment Planning Systems (TPS). Based on the registration results the user can adjust the patient position for reproducible patient positioning relative to the treatment isocenter. During the imaging (simulation) and treatment delivery process, the system continuously calculates the deviations between live- and reference surface for patient motion monitoring to ensure that the patient position remains within pre-defined tolerances.

Indications for use:

The LAP LUNA 3D system is used to support reproducible patient positioning and monitor patient surface motion during radiotherapy and radiosurgery treatments and during CT simulation for radiation therapy planning. LAP LUNA 3D may also be used to guide patients through breath-holds.
The LAP LUNA 3D system can be used for all patients, undergoing radiotherapy and radiosurgery treatments and CT simulation for radiation therapy planning.

Predicate device:

Device Name:	AlignRT Plus
510k number:	K212583
Device Classification Name:	Medical charged-particle radiation therapy system
Product Code:	IYE
C.F.R. Section.:	892.5050
Classification Panel:	Radiology devices
Device Class:	Class II

Comparison to predicate device:
The following table presents the comparison of technological characteristics, functions and parameters of the identified predicate device and the proposed device.

	Vision RT AlignRT Plus	**LAP LUNA 3D**	**Comment**
Indications for use	The AlignRT Plus system is indicated for use to position and monitor patients relative to the prescribed treatment isocenter, and to withhold the beam automatically during radiation delivery. For cranial treatments, a manual head adjuster is included which can be used in concert with AlignRT Plus to provide fine corrections for pitch, roll and yaw rotations. AlignRT Plus is also used to track the patient's respiratory pattern for respiratory synchronized image acquisition, and radiation therapy treatment. Patient contour data can be extracted and exported from the data acquired for the purpose of treatment planning. AlignRT Plus can be calibrated directly to the treatment beam isocenter and in turn assists in performing quality assurance on MV, kV imagers, room lasers and the	The LAP LUNA 3D system is used to support reproducible patient positioning and monitor patient surface motion during radiotherapy and radiosurgery treatments and during CT simulation for radiation therapy planning. LAP LUNA 3D may also be used to guide patients through breath-holds. The LAP LUNA 3D system can be used for all patients, undergoing radiotherapy and radiosurgery treatments and CT simulation for radiation therapy planning.	Similar Even though the Indication for use of the predicate device is more detailed, the core functions remain the same. Both devices are used for positioning the patients and monitoring the patients position during radiotherapy treatment. Both devices can be used to monitor the respiratory pattern of the patients. Both devices can be used to acquire a reference surface or import data to be used as a reference (e.g. DICOM). The LAP LUNA 3D device cannot be used to withhold the beam automatically during radiotherapy. Furthermore, the LAP device comes not with head adjuster for cranial treatment.

	Vision RT AlignRT Plus	**LAP LUNA 3D**	**Comment**
	treatment couch. AlignRT Plus may be used during simulation, setup and stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation is indicated.		
Principle of operation	Video based imaging of 3D skin surface data using surface matching software.	3D imaging of the patients surfaces and comparison with reference surfaces.	Identical
Target population	Any individual (adult or child) undergoing radiotherapy.	Any individual of any age undergoing radiotherapy.	Identical
Components	PC workstation, cables, video cameras. Block Polystyrene (calibration phantom), carbon fibre laminate material (head adjuster).	PC workstation, cables, camera pods (video cameras and a projector unit). Calibration phantom, made of plastic.	Similar The LAP LUNA 3D device does not contain a head adjuster
System performance and accuracy	Positioning accuracy: Target registration errors (as measured using calibration phantom) < 1mm (0.5mm) for all couch angles. Respiratory tracking: Tracks respiratory signal from imaged surface data and sends to CT (4D CT) or to Linac or imaging device (gating). Surface displacements can be tracked with RMS errors < 0.5mm over 10 or more breathing	Planned Positioning accuracy: Target registration errors (as measured using calibration phantom) < 0.5mm for all couch angles. Respiratory tracking: Tracks respiratory signal from imaged surface data. Surface displacements can be tracked with RMS errors < 0.5mm over 10 or more breathing cycles.	Similar The LAP LUNA 3D does not have a gating function.

	Vision RT AlignRT Plus	**LAP LUNA 3D**	**Comment**
	cycles.		
Biocomp	The AlignRT Plus product requires no direct contact with the patient. The only interactions between the user and the system are with: • the PC (in the control room) or remote workstation (in the vault), • the Remote Control (in the vault), • the Real Time Coach (RTC) (in the vault), or • the Head Adjuster (in the vault). • Calibration plate (in the vault) • Calibration cube (in the vault) • Calibration levelling plate (in the vault) The materials of the devices (which are commonly used in light-industrial, commercial and home use) and that the application only involves intermittent external contact with intact skin.	The LUNA 3D device does not come into contact with patients during its intended use. The User does come into contact with commercially available user interfaces such as keyboards or touchscreens of mobile devices. Furthermore, during calibration the user does come into contact with the calibration cube.	Similar The LAP LUNA 3D device does not contain a head adjuster.
Mechanical safety	Cameras are ceiling mounted and do not contact patient or user. The InBore camera solution is fixed to the inside of the bore-based linac. Head	LAP LUNA 3D camera pods are ceiling mounted. Display device is rigidly wall mounted. The breath hold device is clamped to the treatment couch in patient	Similar All components are either rigidly mounted or clamped to the treatment couch.

	Vision RT AlignRT Plus	**LAP LUNA 3D**	**Comment**
	adjuster is clamped to the treatment couch through universal base plate.	environment.	
Optical Pattern	Optical (near infra-red) pattern is projected to patient.	Optical visible blue pattern is projected on the patient's body surface.	Similar Optical pattern is projected on the patient's body surface.
Electrical Standard	IEC 60601-1 compliant.	IEC 60601-1 compliant.	Identical
EMC Standard	IEC 60601-1-2 compliant.	IEC 60601-1-2 compliant.	Identical
Size and Weight	The camera (key part of the system) has the following dimensions: HD Cameras (each) – 470 x 220 x 70 – 4.5kg Horizon cameras (each) – 480 x 140 x 127 – 2.75kg InBore optional camera accessory - Ring 499mm diameter (plus 1mm protrusions) x 177mm wide (max) – 3.2kg	The camera pods have the following dimensions: 540mm x 240mm x 95mm and a weight of 6.4 kg	Similar LAP LUNA 3D system cameras have similar dimensions and weigh as the Align RT horizon camera.
Packaging	The system is packaged in a variety of boxes and then packaged within palletised crate.	System components will be packed separately and commissioned based on the customers order. All components could be send separately or shipped together.	Similar Both devices are provided separately packed and commissioned according to request.
Environmental range	AlignRT Plus is intended for use at altitudes below 3000m (9,842ft). The operating temperature is +16°C to +30°C (60.8° to 86° Fahrenheit). The shipping and storage conditions are - 20°C	<u>Operating</u> Temp: 15..30°C Humidity: 25-80% Altitude: <= 2000m <u>Storage</u> Temp: -10..+40°C	Similar: Both devices have almost identical operating conditions. However the Align RT Device has a broader storage temperature range.

	Vision RT AlignRT Plus	LAP LUNA 3D	Comment
	to +50°C (-4° to 122° Fahrenheit).		
Workstation Operating System	Windows 10	Windows 10 IOT, Windows Server 2022	Similar: Both devices use Windows OS.
Power requirements	110-230V 50/60Hz	110-240V 50/60Hz	Similar: The maximum voltage range of the LAP LUNA 3D is slightly higher, but not relevant for the US market.
Network requirements	10BaseT internet connection behind a local firewall.	100 Mbit/s connected to local hospital network	Similar: LAP LUNA 3D device has a secured 100 Mbit/s network connection to the local hospital network.

Summary of performance testing:
The proposed device has been tested in respect to electrical and mechanical safety in accordance with IEC 60601-1, EMC in accordance with IEC 60601-1-2 and photobiological safety according to IEC 60601-2-57 and IEC 62471 respectively. Non-clinical performance testing in terms of warm-up drift, latency, and multi-camera accuracies of the camera pods has been conducted. The conducted tests verify the compliance to the established technical specifications and support the substantial equivalence to the predicate device.

Conclusion:
LAP GmbH Laser Applikationen believes that the LUNA 3D is substantially equivalent to currently legally marketed devices. The device does not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.