June 4, 2026

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

Re: K253004
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: October 8, 2025
Received: October 9, 2025

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253004

Device Name
LUNA 3D

Indications for Use *(Describe)*
The 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. The LUNA 3D system provides data exchange to radiotherapy imaging and radiotherapy treatment systems to synchronize image acquisition and treatment delivery. LUNA 3D may also be used to guide patients through breath-holds. The 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.

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510(k) Summary K253004

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.

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Date Prepared: 08th of May 2026

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 spatial 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.

The LUNA 3D system may provide data exchange to radiotherapy imaging and radiotherapy treatment devices.

3D motion tracking data acquired by LUNA 3D during a CT imaging scan, can be transferred to the imaging device to support motion synchronized data reconstruction (e.g. 4DCT).

Patient position correction data can be used to send shifts to a motorized couch to correct patient position without manual couch movements prior to treatment start.

During treatment delivery, LUNA 3D motion tracking data can be used to hold the treatment beam, if the patient moves out of pre-defined tolerances. If the patient position is back within the pre-defined tolerances, the treatment can be continued.

Indications for use:

The 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. The LUNA 3D system provides data exchange to radiotherapy imaging and radiotherapy treatment systems to synchronize image acquisition and treatment delivery. LUNA 3D may also be used to guide patients through breath-holds. The 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:	K233622
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 LUNA 3D is considered substantially equivalent to AlignRT Plus (K233622). There is no significant difference in intended use or technology.
The previous version of LUNA 3D (K232031) has been added as reference device, to compare comparable technological features and workflows already covered or addressed in the previous submission of LUNA 3D.

The following table presents the comparison of technological characteristics, functions and parameters of the identified predicate device, reference device and the proposed subject device.

Description/ Parameter	Subject Device: LUNA 3D	Predicate Device: Vision RT AlignRT Plus (K233622)	Reference Device: LUNA 3D (K232031)	Comment
Indications for use	The 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. The LUNA 3D system provides data exchange to radiotherapy imaging and radiotherapy treatment systems to synchronize image acquisition and treatment delivery. LUNA 3D may also be used to guide patients through breath-holds.	The AlignRT Plus system is indicated for: • Tracking respiratory motion throughout the simulation process to facilitate subsequent 4DCT reconstruction and coaching the patient in breathing techniques required for Deep-Inspiration Breath Hold (DIBH). • Verification of patient identity for their radiation treatment session. • Positioning and monitoring of patients during radiation delivery, relative to the setup isocenter and/or the prescribed	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	Similar Both devices are used to track respiration motion during CT simulation processes for breath-hold and synchronized image acquisition (4DCT) Both systems ae use for patient positioning and monitor patient surface motion during radiotherapy and radiosurgery treatments relative to a prescribed isocenter. Both systems can synchronize treatment delivery by automatic beam hold. Both devices can be used to import data

Description/ Parameter	Subject Device: LUNA 3D	Predicate Device: Vision RT AlignRT Plus (K233622)	Reference Device: LUNA 3D (K232031)	Comment
	The LUNA 3D system can be used for all patients, undergoing radiotherapy and radiosurgery treatments and CT simulation for radiation therapy planning.	treatment isocenter. • Withholding the beam automatically during radiation delivery, as well as gating the beam based on the patient's respiratory motion. • Performing quality assurance on MV, kV imagers, room lasers, and the treatment couch. • Visualizing the Cherenkov signal associated with the radiation beam on entry and exit from the patient. • Passing and receiving information to/from other systems associated with the radiotherapy treatment.	therapy planning.	from other systems to be used as a reference (e.g. DICOM). The already cleared version of LUNA 3D (reference device) has the same core functions as the subject and the predicate device. However, in its current version, the reference device has no interoperability with treatment or diagnostic devices. Compared to the reference device, LUNA 3D does not verify the patient identity and is not visualizing Cherenkov signals.
Principle of operation	3D imaging of the patients surfaces and comparison with reference surfaces.	Video based imaging of 3D skin surface data using surface matching software.	3D imaging of the patients surfaces and comparison with reference surfaces.	Similar to predicate device and identical to reference device
Target population	Any individual of any age undergoing radiotherapy.	Any individual (adult or child) undergoing radiotherapy.	Any individual of any age undergoing radiotherapy.	Similar to predicate device and identical to reference device
Components	PC workstation, cables, camera pods (video cameras and a projector unit). Calibration phantom, made of plastic. Depending on the interoperability, additional hardware such as cables and	PC workstation, cables, camera pods (video cameras and a projector unit). Calibration phantom, made of plastic. Depending on the interoperability, additional hardware such as cables and	PC workstation, cables, camera pods (video cameras and a projector unit). Calibration phantom, made of plastic.	Similar The components provided with the system are comparable. All three devices (the reverence device as well) have the basic setup with cameras, cables and computer workstations.

Description/ Parameter	Subject Device: LUNA 3D	Predicate Device: Vision RT AlignRT Plus (K233622)	Reference Device: LUNA 3D (K232031)	Comment
	adapter devices can be provided.	adapter devices can be provided.		To allow interoperability with treatment and diagnostic devices, the subject and the predicate device might be delivered with additional hardware.
System performance and accuracy	Shift accuracy* multi pod system: <0.5mm Rotation accuracy* multi pod system: <0.5mm	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 (4 D CT) or to Linac or imaging device (gating). Surface displacements can be tracked with RMS errors < 0.5mm over 10 or more breathing cycles.	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.	Identical Both the predicate device and the subject device have a gating function; Similar The accuracy of the subject device is better than the predicate device's and identical to the reference device.
Biocomp	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.	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 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.	Identical

Description/ Parameter	Subject Device: LUNA 3D	Predicate Device: Vision RT AlignRT Plus (K233622)	Reference Device: LUNA 3D (K232031)	Comment
		• 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.		
Mechanical safety	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 environment.	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 adjuster is clamped to the treatment couch through universal base plate.	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 environment.	Identical, except subject and reference device have no InBore camera
Optical Pattern	Optical visible blue pattern is projected on the patient's body surface.	Optical (near infra-red) pattern is projected to patient.	Optical visible blue pattern is projected on the patient's body surface.	Similar, only different wavelength Optical pattern is projected on the patient's body surface.
Electrical Standard	IEC 60601-1 compliant.	IEC 60601-1 compliant.	IEC 60601-1 compliant.	Identical
EMC Standard	IEC60601-1-2 compliant.	IEC 60601-1-2 compliant.	IEC 60601-1-2 compliant.	Identical
Size and Weight	The camera pods have the following dimensions: 540mm x 240mm x 95mm and a weight of 6.4 kg	The camera (key part of the system) has the following dimensions: HD Cameras (each) – 470 x 220 x 70 – 4.5kg	The camera pods have the following dimensions: 540mm x 240mm x 95mm and a weight of 6.4 kg	Similar LUNA 3D system cameras have similar dimensions and weight as the Align RT Horizon

Description/ Parameter	Subject Device: LUNA 3D	Predicate Device: Vision RT AlignRT Plus (K233622)	Reference Device: LUNA 3D (K232031)	Comment
		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		camera.
Packaging	System components will be packed separately and commissioned based on the customers order. All components could be send separately or shipped together.	The system is packaged in a variety of boxes and then packaged within palletized 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	Operating Temp: +15 to +30°C Humidity: 25-80% Altitude: <= 2000m Storage Temp: -10 to +40°C	Operating Temp: +16°C to +30° Altitude: <= 3000m Storage - 20°C to +50°C	Operating Temp: +15 to +30°C Humidity: 25-80% Altitude: <= 2000m Storage Temp: -10 to +40°C	Similar: Both devices have almost identical operating conditions. However the Align RT device has a broader storage temperature range.
Workstation Operating System	Windows 10 IOT, Windows Server 2022	Windows 10	Windows 10 IOT, Windows Server 2022	Similar: Both devices use Windows OS.
Power requirements	110-240V 50/60Hz	110-230V 50/60Hz	110-240V 50/60Hz	Similar: The maximum voltage range of the LUNA 3D is slightly higher, but not relevant for the US market.
Network requirements	100 Mbit/s connected to local hospital network	10BaseT internet connection behind a local firewall.	100 Mbit/s connected to local hospital network	Similar: LUNA 3D device has a secured 100 Mbit/s network connection whereas the subject device has 10BaseT. Thus the subject device does offer better transmissions speed.

Summary of bench testing:

The new functions of the subject device, compared to the already cleared reference device in terms of synchronized treatment (gating function), synchronized image acquisition (4DCT) and couch control have been tested on a functional level, performance level and in terms of human factors. The tests have been carried out on production equivalent systems in laboratory and clinical environments.

LUNA 3D has undergone formal hardware and software verification and validation testing. The testing was performed in accordance with LAPs development SOP, that is part of the company wide quality management system compliant to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System Standard and the ISO 14971 Risk Management Standard. The Test results demonstrate the device performance as intended.

For latency measurement it was evaluated if the specified mean latency between patient movement and an update to the displayed values can be achieved. A representative setup was used on-site to measure latency values under expected clinical conditions. To determine system latency, the time difference between triggering the capture of camera images in the pod and the display of the results on the screen, or the transmission of the signal to the third-party interface, is measured. The latency tests confirmed the specified latency.

In the accuracy tests, the 3D sensors should be capable of achieving the specified displacement detection accuracy and the specified rotation detection accuracy in a system with multiple camera pods during positioning and monitoring operations. To determine this, a representative setup was used on-site to measure accuracy values under expected clinical conditions. A phantom was placed on a motion platform with six degrees of freedom in the isocenter and moved in a defined manner. Camera pod data was acquired and accuracy determined. The tests demonstrated a tracking accuracy within the specified accuracy in a multi-camera pod system during positioning and monitoring.

Essential performance was tested in a functional safety lab test under the supervision of a certified testing organization. The purpose of this test was to verify that the essential performance characteristics were maintained even under single fault conditions. Latency and accuracy measurement in connection with the display of values and the gating function was carried out and specified single-fault conditions were induced. It was determined that the defined essential performance parameters were maintained under single fault conditions.

Validation in a clinical setting included acceptance testing of the gating function and the reliable display of values, a verified full workflow simulation, object tolerance tests, and thus the functional validation of LUNA 3D in a clinically equivalent environment.
The complete clinical workflow with the gating function was simulated in a clinical setting. Among other things, an object was moved into and out of the tolerance range. The response of the beam signal is measured and should fall within the specified tolerance limits. The signal was measured as expected at the third party interface.
In addition, the 4DCT functionality and automated table control were validated in a clinical

environment to ensure that the table moves according to the data provided by the system. The complete clinical workflow was simulated. A breathing phantom was used to generate baseline data, which was then synchronized with the CT scanner as respiratory motion data. The respiratory data was recorded during the CT scan. The data were acquired as expected. To verify the functionality of the table control, the table was moved automatically based on the data provided by LUNA 3D. For this purpose calculated correction values were sent from LUNA 3D and the table was supposed to move to the respective position accordingly. The table moved to the intended positions. This confirmed the LUNA 3D functionalities of gating, 4DCT, and couch control in a clinical setting and in accordance with the intended workflows.

To verify that the intended users can operate the LUNA 3D user interface correctly, usability tests were conducted in accordance with FDA guidelines on human factors. This served to evaluate the ergonomic aspects of new workflows and functions, as well as to identify potential user errors. A representative group of users was trained in the clinically relevant workflows. Subsequently, these steps were performed by the user in a clinical setting under observation, and the implementation was documented. No safety-related user errors were observed.

Comparison of electrical safety and electromagnetic compatibility:
The subject device is electrically and electromagnetically safe and in accordance with internationally recognized standards of the IEC 60601 standard family. Both predicate as well as the proposed device follow identical standards, whereas the proposed device follows the current version that is included in the list of recognized consensus standards.

FDA recognized consensus standards used:
- ANSI AAMI ES ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] 19-46
- IEC 60601-1-2 Edition 4.1 2020-09 Consolidated Version 19-36
- IEC TR 60601-4-2 Edition 1.0 2016-05 19-19
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION 13-79
- ANSI AAMI ISO 14971:2019 5-125

Conclusion:
LAP GmbH Laser Applikationen believes that the LUNA 3D is substantially equivalent to the currently legally marketed device.
Carried out tests in laboratory and clinical environment, show the same or better performance and accuracy values compared to the predicate device. The safety tests were conducted and passed in accordance with the same standards that were applied to the predicate device. The subject device does not introduce new indications for use, compared to the predicate device. It has the same technological characteristics and does not introduce new potential hazards or safety risks.
Therefor the subject device is considered to be as safe and as effective, and it performs as well as or better than the legally marketed device.