LAP GmbH Laser Applikationen
% Martin Pfabel
Director Quality Management & Regulatory Affairs
Zeppelinstrasse 23
LUENEBURG, GERMANY 21337

September 14, 2018

Re: K173926
Trade/Device Name: DORADOnova MR3T
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: August 16, 2018
Received: August 20, 2018

Dear Mr. Pfabel:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173926

Device Name
DORADOnova MR3T

Indications for Use *(Describe)*
The DORADOnova MR3T system assists in reproducible patient positioning during radiation therapy planning and is utilized during treatment planning workflow. The DORADOnova MR3T system projects visual laser beams which can be positioned at specified coordinates via a control system. The position coordinates are typically chosen by the operator or provided by an external system (e.g. treatment planning system). The DORADOnova MR3T system is allowed to be used in MR environment with a magnetic field, less or equal to 3 Tesla.

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 LAP moving laser positioning system meets the requirements of 21 CFR 807.92.

Submitter information:

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Date Prepared: September 13th, 2018

Device(s) Identification:

Device trade name:	DORADOnova MR3T
Common name:	Radiotherapy positioning system

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 LAP moving laser positioning system contains laser devices and a control system. The laser system is provided in a configuration that enables the movement of two projection planes by using an appropriate composition of motorized and fixed laser devices. The installation of the system is realized in a combined bridge solution.

Indications for use:

The DORADOnova MR3T system assists in reproducible patient positioning during radiation therapy planning and is utilized during treatment planning workflow. The DORADOnova MR3T system projects visual laser beams which can be positioned at specified coordinates via a control system. The position coordinates are typically chosen by the operator or provided by an external system (e.g. treatment planning system). The DORADOnova MR3T system is allowed to be used in MR environment with a magnetic field, less or equal to 3 Tesla.

Predicate device:

Device Name:	AlignRT
510k number:	K052682
Device Classification Name:	System, radiation therapy, charge-particle
Product Code:	IYE
C.F.R. Section.:	892.5050
Classification Panel:	Radiology devices
Device Class:	Class II

Reference device:

Device Name:	CT Sim Laser Alignment System
510k number:	K152303
Device Classification Name:	Light beam patient position indicator
Product Code:	IWE
C.F.R. Section.:	892.5780
Classification Panel:	Radiology devices
Device Class:	Class I

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

Parameter	Predicate device Vision RT AlignRT	Reference device CT Sim Laser Alignment System	Proposed device DORADOnova MR3T	Evaluation
Intended Use	The AlignRT system is used to position patients at the isocentre of the linear accelerator for radiation therapy procedures. Patient contour data can be extracted and exported from the acquired data for the purpose of treatment planning AlignRT is used by radiotherapy professionals in appropriate hospital environments It can be used with all types of radiotherapy patients and can image any visible anatomical region. The system is completely noninvasive and does not require the application of any external markers to the patient.	The CT Sim Laser System is used in the simulation stage of radiation therapy to prepare a patient for treatment. The lasers can be moved to a point that defines the isocenter in the CT suite. The Gammex CT Sim is intended to read laser positioning coordinates in a Gammex specified software format from a file in a shared folder. Typically the coordinates were calculated by a Radiation Therapy Treatment Planning System (RTPS) using CT images and sent to the Hospital Information System (HIS), Oncology System (OIS) or other system, by the RTPS.	The DORADOnova MR3T system assists in reproducible patient positioning during radiation therapy planning and is utilized during treatment planning workflow. The DORADOnova MR3T system projects visual laser beams which can be positioned at specified coordinates via a control system. The position coordinates are typically chosen by the operator or provided by an external system (e.g. treatment planning system). The DORADOnova MR3T system is allowed to be used in MR environment with a magnetic field, less or equal to 3 Tesla.	Similar The devices are intended to be used during treatment planning to assist in patient positioning for radiation therapy procedures. In addition AlignRT is used to assure patients reproducible positioning during radiation therapy procedures. The devices achieve their intended use completely noninvasive and are not limited to certain types of radiotherapy patients. Both devices are intended to be used in a hospital environment by professional medical staff, involved in treatment of radiotherapy patients. Patient data can be received from treatment planning systems.

Parameter	**Predicate device** Vision RT AlignRT	**Reference device** CT Sim Laser Alignment System	**Proposed device** DORADOnova MR3T	**Evaluation**
Functional principle	Projection of a visual light pattern on the patient's skin surface. The pattern is detected by two 3D cameras to determine the patient's position relative to a stored reference image.	Projection of a visual laser lines on the patient's skin surface. Reflection of the laser lines aide's professional medical staff to determine the patient's position.	Projection of a visual laser lines on the patient's skin surface. Reflection of the laser lines aide's professional medical staff to determine the patient's position.	Similar The devices project visual light on the patient's skin. Its reflection is used to determine the position of the patient relative to the treatment device. Whereas the Predicate device projects a visual light pattern that consists of pattern of points, the proposed device and the reference device use laser sources to create 3 specific intersection points, projected on the patient skin. Therefore, the functional principle can be regarded as equivalent.
Patient reference position information	The patient reference position information is a reference surface image. It is acquired either by the device or imported from a treatment planning system. A surface image consisting of thousands of points is acquired at the treatment device and compared to the reference image for reproducible patient positioning on the treatment device.	The patient reference position information is the coordinates for 3 laser intersection points. They are either manually input into the device by the operator or imported from the treatment planning system. External fiducial markers are placed on the surface of the skin at the 3 laser intersection points for reproducible patient positioning on external patient alignment lasers on the treatment device.	The patient reference position information is the coordinates for 3 laser intersection points. They are either manually input into the device by the operator or imported from the treatment planning system. External fiducial markers are placed on the surface of the skin at the 3 laser intersection points for reproducible patient positioning on external patient alignment lasers on the treatment device.	Similar In all devices, patient reference position information is either created during the workflow by the operator or the device itself or is imported from the treatment planning system.

Parameter	Predicate device Vision RT AlignRT	Reference device CT Sim Laser Alignment System	Proposed device DORADOnova MR3T	Evaluation
Prescription use only	yes	yes	yes	Identical
Target population	Any individual (adult or child) undergoing radiotherapy.	Any individual (adult or child) undergoing radiotherapy.	Any individual (adult or child) undergoing radiotherapy.	Identical
User interface	Desktop-PC	Tablet, Desktop-PC	Desktop PC with Touchscreen	Identical
Projection sources	2 or 3	3 or 5	3	Similar Reference device can have two additional projection sources
TPS Data Import	DICOM	Text & DICOM	Text & DICOM	Similar While the predicate device is capable of importing DICOM data, the reference and the Proposed device are also capable of importing data in text format
Device setup	Projection sources and 3D cameras rigidly mounted to the ceiling.	Projection sources rigidly mounted to the ceiling, wall, post or bridge setup	Projection sources rigidly mounted as a bridge setup	Similar All devices are rigidly mounted in the diagnostic or treatment room they are used in. The devices are mounted to the ceiling, the walls or the floor. All devices require an installation process. In addition, the reference and the proposed devices sources are capable of controlled movement inside the devices housing.
Resolution/ line width	<1 mm	<1 mm at 4m distance	0.5 mm (blue) at 4m distance <1 mm (red&green) at 4m distance	Similar

Parameter	Predicate device Vision RT AlignRT	Reference device CT Sim Laser Alignment System	Proposed device DORADOnova MR3T	Evaluation
Positioning accuracy	System accuracy: Errors along each of 3 axes of treatment: max mean: 0.27mm; max std dev: 0.65mm.	+/- 0.1 mm	+/- 0.1 mm	Similar
Bio-compatibility	No contact with patient	No contact with patient	No contact with patient	Identical
Anatomical use sites	Entire body surface	Entire body surface	Entire body surface	Identical
Compatibility with the environment and other devices	Cleared for use in hospital environment	Cleared for use in hospital environment	For use in hospital environment, including MRI environment up to and including 3 Tesla.	Similar The proposed device can also be used in MR environment up to and including three Tesla. MRI safety testing and labeling of the proposed device are in accordance with applicable ASTM standards. Bench testing in MR environment up to three Tesla did not show any negative impact on the performance of the proposed device.
Laser Class	Laser specific (predicate device does not contain laser)	2	2	Identical
Available laser colors	Laser specific (predicate device does not contain laser)	red, green, blue	red, green, blue	Identical
Line length (distribution angle)	Laser specific (predicate device does not contain laser)	>2m at 4m (30°)	3m at 3m (53°)	Similar The wider distribution angle leads to a longer line length. This would equal 4m at 4m.

Parameter	Predicate device Vision RT AlignRT	Reference device CT Sim Laser Alignment System	Proposed device DORADOnova MR3T	Evaluation
				Therefore the safety and effectiveness is not impaired in comparison to the predicate device.

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 laser safety in accordance with IEC 60825-1. MRI safety has been tested in accordance with applicable ASTM standards. The proposed device complies with U.S. performance standard 21CFR 1040.10.

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