LAP GmbH Laser Applikationen
% Mr. Martin Pfabel
Director Quality Management & Regulatory Affairs
Zeppelinstrasse 23
21337 Lueneburg, Lower Saxony
GERMANY

June 3, 2020

Re: K200907
Trade/Device Name: Thales 3D MR Scanner
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: March 31, 2020
Received: April 6, 2020

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/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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200907

Device Name
THALES 3D MR SCANNER

Indications for Use *(Describe)*

The THALES 3D MR SCANNER system is designed to measure the characteristic radiation beam for an irradiation unit. The beam data is stored in the software program and can be exported from there for use during commissioning in a treatment planning system (TPS) or for quality assurance. The THALES 3D MR SCANNER system can be used with irradiation units with integrated magnetic resonance imaging and a magnetic field of less than or equal to 0.35 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 THALES 3D MR Scanner meets the requirements of 21 CFR 807.92.

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Date Prepared: 31 March 2020

Device(s) Identification:

Device trade name:	THALES 3D MR scanner
Common name:	3D water phantom

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 THALES 3D MR SCANNER system consists of a water phantom with a carriage system, a manual control unit and a software program. A water basin with the corresponding pump, a control unit with an electrometer, and a motor controller are integrated in the carriage system. The software program is used to control the three axes of the water basin, perform measurements and analyse measured data.
The software program has the following properties: Acquisition of measured data, analysis, and recording of photon beams with the water phantom. Generation and export of beam data libraries for a treatment planning system (TPS) for commissioning of irradiation units. The software program is equipped with a central database and/or a file system for central storage of all recorded data for different irradiation units within a large hospital network with different sites. The software program offers the option of defining different user levels to support the typical clinical workflows.

Indications for use:

The THALES 3D MR SCANNER system is designed to measure the characteristic radiation beam for an irradiation unit. The beam data is stored in the software program and can be exported from there for use during commissioning in a treatment planning system (TPS) or for quality assurance. The THALES 3D MR SCANNER system can be used with irradiation units with integrated magnetic resonance imaging and a magnetic field of less than or equal to 0.35 tesla.

Predicate device:

Device Name:	BEAMSCAN MR
510k number:	K191646
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.

Parameter	**Predicate device** BEAMSCAN MR	**Proposed device** THALES 3D MR Scanner	**Evaluation**
Intended Use	The PTW water phantom system BEAMSCAN MR is intended for dosimetry measurements in radiotherapy systems. The device is intended to determine the beam characteristics of the radiotherapy system (beam data acquisition) during the commissioning and/or for periodic quality assurance procedures according to the QA plan of the responsible medical physicist. The system can also be used at combined MRI-Radiation Therapy systems with static magnetic fields of up to 1.5T.	The THALES 3D MR SCANNER system is designed to measure the characteristic radiation beam for an irradiation unit. The beam data is stored in the software program and can be exported from there for use during commissioning in a treatment planning system (TPS) or for quality assurance. The THALES 3D MR SCANNER system can be used with irradiation units with integrated magnetic resonance imaging and a magnetic field of less than or equal to 0.35 tesla.	**Similar** The intended use of both systems covers the quality assurance for radiation therapy systems as part of regular quality checks, commissioning or other occasions. Both systems are further indicated for use with integrated magnetic resonance imaging of magnetic field. The predicate device is indicated to be used in combined MRI-Radiation therapy systems with static magnetic fields up to 1.5 Tesla. The proposed device can be used with irradiation units with integrated magnetic resonance imaging and a magnetic field of less than or equal to 0.35 tesla.
Scanning range	408mm * 355mm * 248mm (model for ViewRay)	380mm * 380mm * 242mm	**Similar** The scanning ranges are nearly identical

Parameter	**Predicate device** BEAMSCAN MR	**Proposed device** THALES 3D MR Scanner	**Evaluation**
Tank shape	Square	Square	**Identical**
Wall material	PMMA	PMMA	**Identical**
Chamber holder orientation	Horizontal and vertical	Horizontal and vertical	**Identical**
Motor scanning mode	Step by step	Step by step	**Identical**
Step size	0.1mm	0.1mm	**Identical**
Maximum speed	30mm/s	40mm/s	**Similar** The THALES system has a higher maximum speed which allows a faster scanning process
Position accuracy	+/-0.1mm	+/- 0.25mm (at 0.35Tesla)	**Similar** The difference in accuracy does not affect the safety or the effectiveness of the proposed system. The construction requirements on phantoms in accordance with IEC 60731 have been met.
Reproducibility	+/-0.1mm	+/- 0.25mm (at 0.35Tesla)	**Similar** The difference in reproducibility does not affect the safety or the effectiveness of the proposed system. The construction requirements on phantoms in accordance with IEC 60731 have been met.
MRI compatible	Up to 1.5 Tesla	Up to 0.35 Tesla	**Different** The LAP system is indicated for use with integrated magnetic resonance imaging of magnetic fields less or equal than 0.35T

Parameter	**Predicate device** BEAMSCAN MR	**Proposed device** THALES 3D MR Scanner	**Evaluation**
			while the predicate device is indicated to be used in a static magnetic field up to 1.5 Tesla. The difference in MR compatibility does not affect the safety or effectiveness of the system while the target system of the proposed device (ViewRay MRidian) only provides a static magnetic field of 0.35 Tesla or less. LAP has tested the performance and safety aspects with the target system and can confirm that the proposed device can be used in the respective MRI environment.
Electrometer channels	2 entries	2 entries	**Identical**
Electrometer resolution	10 fA	1 fA	**Different** The electrometer resolution for the proposed device is better (10x better) than the predicate device's.
Electrical safety	IEC 61010	IEC 61010	**Identical**
Dosimeter testing	IEC 60731	IEC 60731	**Identical**
Electromagnetic compatibility	IEC 60601-1-2:2007	IEC 60601-1-2:2015	**Identical**

Summary of performance testing:
The proposed device has been tested in respect to electrical and mechanical safety in accordance with IEC 61010, EMC in accordance with IEC 60601-1-2 and dosimeter requirements in accordance with IEC 60731. MRI safety has been tested in accordance with applicable ASTM standards.

Conclusion:
LAP GmbH Laser Applikationen believes that the THALES 3D MR Scanner 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.