February 21, 2020

PTW-Freiburg Physikalisch-Technische-Werkstaetten-Dr. Pychlau GmbH
% Sandor-Csaba Ats
Regulatory Affairs Manager
Loerracher Strasse 7
79115 Freiburg, BW
GERMANY

Re: K191646
Trade/Device Name: BEAMSCAN MR
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: January 14, 2020
Received: January 17, 2020

Dear Sandor-Csaba Ats:

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,

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)*
K191646

Device Name
BEAMSCAN MR

Indications for Use *(Describe)*

The BEAMSCAN MR system is used preferably in combined MRI-radiation therapy systems with static magnetic fields of up to 1.5T and is intended to collect beam data in water under the aspect of machine QA for the following purposes:

- acceptance testing and/or commissioning of a combined MRI-radiation therapy system

- measurements after repair or replacement of major treatment unit components of a combined MRI-Radiation therapy system

- beam data analysis according to international therapy dosimetry protocols

- acquisition, formatting and transfer of basic data to treatment planning systems

- periodic QA procedures, e.g. constancy check

- high precision data acquisition for scientific research (not a medical device indication)

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

K191646

1.	Applicant:	PTW-Freiburg Physikalisch-Technische-Werkstaetten Dr. Pychlau GmbH
2.	Address:	Loerracher Strasse 7 79115 Freiburg Germany www.ptw.de
3.	Contact Person:	Dr. Sándor-Csaba Áts Tel. +49 (0) 761 49055 896 sandor.ats@ptw.de
4.	Preparation Date:	June 14, 2019
5.	Device Name:	BEAMSCAN MR
6.	Proprietary Name:	BEAMSCAN MR
7.	Common Name:	Water Phantom
8.	Classification:	Regulation number: 21 CFR 892.5050 Name: Medical charged-particle radiation therapy system, Product Code: IYE
9.	Predicate Device:	K161807 BEAMSCAN water phantom system PTW Freiburg
10.	Device Description:	The BEAMSCAN MR system is comprised of a PMMA tank with a moving mechanism and radiation detectors. Further main components are a carriage with built-in electrometer, control unit and control interface. The carriage includes a water reservoir. The whole system is controlled by software for data display and processing.
11.	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

12.	Indications:	The BEAMSCAN MR system is used preferably in combined MRI-radiation therapy systems with static magnetic fields of up to 1.5T and is intended to collect beam data in water under the aspect of machine QA for the following purposes: – acceptance testing and/or commissioning of a combined MR-radiation therapy system. – measurements after repair or replacement of major treatment unit components of a combined MRI-radiation therapy system – beam data analysis according to international therapy dosimetry protocols – acquisition, formatting and transfer of basic data to treatment planning systems – periodic QA procedures, e.g. constancy check – high precision data acquisition for scientific research (not a medical device indication)
13.	Contraindications:	The BEAMSCAN MR system is intended for QA purposes and must not be used while a patient is present. It must not be used for Particle Beam dosimetry nor for Diagnostic Radiology. It must not be used while an MR-Linac is taking MR-images The resulting measurement data must not be used to control the radiotherapy device.
14.	Intended User:	The BEAMSCAN MR system must be used only by qualified personnel, usually the medical physicist responsible for the radiotherapy system or an authorized person.
15.	Summary of the Product Change:	The intended use is the same compared to the predicate device but will be carried out within a MR Radiation Therapy system.
	Differences to the predicate devices:	In order to use the device with a MR-linac, the PMMA tank was made to be removable for putting it on the linac treatment table and the size was adapted to move it into the MRT tube. This led to a smaller size of the entire device. Ferromagnetic components were replaced by non-ferrous material to finally be “MR conditional” in a static 1.5 Tesla magnetic field. The software contains no new functions.
16.	Performance Data:	The FDA has not published any performance standards for this product.
	Biocompatibility:	The device is used for pre-treatment quality assurance while no patient is present. Since the contact of the operator with the device occurs only with uninjured skin and the surface of the device components contains no critical material, the contact with the operator is biologically uncritical.

Electrical & mechanical safety and electromagnetic compatibility (EMC):	Electrical safety, EMC testing and MR safety testing were conducted by independent test laboratories. BEAMSCAN MR is certified as in compliance with IEC 61010-1:2010 (with no patient contact of the product the focus is directed to user safety) and IEC 60601-1-2:2014 (emission and immunity) according to IEC/CISPR 11:2009 (modified + A1:2010). MR safety testing was performed according to ASTM F2052-15.
Software Verification and Validation Testing:	Software verification and validation testing results were conducted and submitted according to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005). The BEAMSCAN software contains no new functions and was previously cleared with 510(k) #K161807 and is thus not part of this submission.
Bench and Non-clinical Testing:	Verification and validation testing demonstrated that BEAMSCAN MR fulfils the design specification and its intended use. Non-clinical performance testing was performed according to IEC 60731:2016 and to specific properties of water phantom systems which included radiotherapy dose measurements i.e. with step by step measurements and also measurement accuracy with respect to detector positioning, reproducibility and mechanical alignment. The verification of the design output against the design input was performed in BEAMSCAN MR system testing. Validation of the clinical workflow has been conducted in BEAMSCAN MR validation testing with qualified medical physicists and experienced PTW staff. Testing with a patient present was not required since BEAMSCAN MR acts as a pre-treatment quality assurance tool while no patient is present.
17. Conclusions:	The comparison of the indications for use, the technological characteristics, the performance, safety and effectiveness of the predicate and the subject device has shown that, when used within a MR Radiation Therapy system, the PTW BEAMSCAN MR system is as safe and effective as the predicate device within a non-MR environment.