DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Ptw-Freiburg Physikalisch Technische-Werksraetten Dr. Pychlau GmbH
% Dr. Sandor-Csaba Ats
Regulatory Affairs Manager
Loerracher Strasse 7
Freiburg, BW 79115
GERMANY

May 19, 2017

Re: K161807
Trade/Device Name: BEAMSCAN
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: May 10, 2017
Received: May 15, 2017

Dear Dr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For
Robert 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161807

Device Name
BEAMSCAN

Indications for Use *(Describe)*

The BEAMSCAN system 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 radiation therapy system.
- measurements after repair or replacement of major treatment unit components.
- 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 checks.

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

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:	May 10, 2017
5.	Device Name:	BEAMSCAN
6.	Proprietary Name:	BEAMSCAN
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:	K954165 PTW-MP3 & PTW-MP3S AUTOMATIC WATER PHANTOM PTW Freiburg
10.	Device Description:	The BEAMSCAN system is comprised of a PMMA tank with a moving mechanism and a radiation detector. Further main components are a lifting carriage with built-in electrometer and control unit with separate control pendant. The lifting carriage either includes a water reservoir or a separate reservoir is used. A positioning device can be mounted on top of the lifting carriage and allows the water phantom to be aligned manually. The whole system is controlled with software for data display and processing.
11.	Intended Use:	The PTW water phantom system (BEAMSCAN) is intended for dosimetry measurements in the context of a radiotherapy system. 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.

12.	Indications:	The BEAMSCAN system 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 radiation therapy system. – measurements after repair or replacement of major treatment unit components. – 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 checks.
13.	Contraindications:	The BEAMSCAN system is for QA purposes and must not be used while a patient is present. It must not be used for Particle Beam dosimetry, for Diagnostic Radiology, and in an MR environment. The resulting measurement data must not be used to control the radiotherapy device
14.	Intended User:	The BEAMSCAN system must be used only by qualified personnel as medical physicists.
15.	Substantial equivalence	While the wording is not identical, the intended use, the indications for use and the characteristics of this device are substantively the same as of the predicate devices identified on the comparison chart, which is provided with the premarket notification submission. It is our opinion that BEAMSACAN does not have functions and technological characteristics that raise additional types of questions related to terms of safety and effectiveness.
	Differences to the predicate devices:	Aggregation of all formerly discrete components, e.g. water phantom tank, electrometer, several control units, all cables and water reservoir, to one physical unit and replacing cable by wireless connection. Automated levelling by calculating ideal coordinate axes with respect to the measured water surface. Continuous measuring alternatively to repeatedly positioning of the detector and subsequent measuring at discrete measuring points. Improved dosimetry detector with respect to 3D characteristics. No additional type of safety issue is raised by these changes.
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 and EMC testing were conducted by independent test laboratories. BEAMSCAN 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 60601-1-2:2007 (emission and immunity) / CISPR 22:2008 (RF technology) and 47 CFR Part 15 Subpart B.
	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).
	Bench and Non-clinical Testing:	Verification and validation testing demonstrated that BEAMSCAN fulfils the design specification and its intended use. Non-clinical performance testing was performed according to IEC 60731 A1:2016 and to specific properties of water phantom systems which included radiotherapy dose measurements i.e. with step by step and continuous 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 system testing. Validation of the clinical workflow has been conducted in BEAMSCAN validation testing with qualified medical physicists and experienced PTW staff. Testing with a patient present was not required since BEAMSCAN acts as a pre-treatment quality assurance 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 the PTW BEAMSCAN water tank system is as safe and effective as the predicate device and that the application is as well or better. With respect to the use the device do not raised new questions of safety and effectiveness.