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

May 31, 2024

Re: K232738
Trade/Device Name: BeamDose software (S080053); BEAMSCAN software, option reference dosimetry (S080054.002)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: April 26, 2024
Received: April 30, 2024

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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232738

Device Name
BeamDose software (S080053);
BEAMSCAN software, option reference dosimetry (S080054.002)

Indications for Use *(Describe)*
BeamDose is a software for the following purposes in radiotherapy:
– absolute dose measurements as field class dosemeter (according to IEC 60731)
– monitor calibration
– positioning of detectors in PTW water phantoms

The software enables the user of a BEAMSCAN, TANDEM, TANDEM XDR, UNIDOS E, UNIDOS webline, UNIDOS Tango, UNIDOS Romeo or MULTIDOS electrometer to operate the electrometer as a therapy dosemeter in accordance with IEC 60731.
The software establishes the communication with the electrometer, provides calibration and correction factors for various detectors and displays the measurement results.
Additionally, the software enables the positioning of a measuring detector in the desired measuring depth with a motorized PTW water phantom.

The measured absolute dose values must not be used directly in radiation therapy.
They have to be checked for plausibility by qualified personnel.

The software must be used only by qualified personnel, usually the medical physicist responsible for the radiotherapy system or an authorized person.

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.

Executive Summary

1 Submitter's Information

Company name:	PTW-Freiburg Physikalisch-Technische-Werkstaetten Dr. Pychlau GmbH
Company address:	Loerracher Strasse 7, 79115 Freiburg, Germany
Contact name:	Dr. Sándor-Csaba Áts (Regulatory Affairs Manager)
Contact phone:	+49 761 49055-896
Proprietary name:	BeamDose software (S080053); BEAMSCAN software, option reference dosimetry (S080054.002)
Common name:	Reference dosimetry software
510(k) number:	K232738
Regulation number:	21 CFR 892.5050
Regulation name:	Medical charged-particle radiation therapy system
Classification name:	Accelerator, Linear, Medical
Product code:	IYE
Device class:	Class II

Date of preparing this summary: 2024-05-31

2 Predicate Device Information

Proprietary name:	DoseView 3D
Common name:	Water Phantom Scanning System
510(k) number:	K103193
Regulation number:	21 CFR 892.5050
Regulation name:	Medical charged-particle radiation therapy system
Classification name:	Accelerator, Linear, Medical
Product code:	IYE
Device class:	Class II
Manufacturer:	Standard Imaging, Inc.
Submitted:	December 27, 2010

3 Device Description

The software measures with BEAMSCAN, TANDEM, TANDEM XDR, UNIDOS E, UNIDOS webline, UNIDOS Tango, UNIDOS Romeo, and MULTIDOS and calculates absolute dose values.

The software controls the positioning of detectors in BEAMSCAN, MP3, MP2, and MP1 water phantoms.

The software comprises the readout of the detector data from a data base (Detector Library) with calibration factors and other detector parameters.

The software corrects measurement data according to temperature and atmospheric pressure and with user correction factor.

The software supports RS232 and TCP/IP interfaces to read out measurement data from the electrometers and to operate the water phantoms.

4 Intended Use Statement

BeamDose is a software for the following purposes in radiotherapy:

- absolute dose measurements as field class dosemeter (according to IEC 60731)
- monitor calibration
- positioning of detectors in PTW water phantoms

The software enables the user of a BEAMSCAN, TANDEM, TANDEM XDR, UNIDOS E, UNIDOS webline, UNIDOS Tango, UNIOS Romeo or MULTIDOS electrometer to operate the electrometer as a therapy dosemeter in accordance with IEC 60731.

The software establishes the communication with the electrometer, provides calibration and correction factors for various detectors and displays the measurement results.

Additionally, the software enables the positioning of a measuring detector in the desired measuring depth with a motorized PTW water phantom.

The measured absolute dose values must not be used directly in radiation therapy. They have to be checked for plausibility by qualified personnel.

The software must only be used by qualified personnel, usually medical professionals including, radiologists, nuclear medicine physicians, radiation oncologists, dosimetrists and medical physicists or authorized persons.

5 Substantial Equivalence

5.1 Technological Characteristics

Both, the Standard Imaging software and the PTW software are software to control water phantoms and collect data from electrometers for quality assurance in radiation therapy. Its technological characteristics are equivalent to the Standard Imaging software.

In combination with a water phantom and an electrometer the BeamDose software is for

- absolute dose measurements as field class dosemeter (according to IEC 60731)
- monitor calibration
- positioning of detectors in PTW water phantoms

The DoseView 3D system also consists among others of a controlling software, a water phantom and an electrometer, which is used for

- Collection of dose depth data for radiation treatment planning system use.
- Completion of clinical dosimetry protocols and calibrations.

This corresponds to the intended use of the BeamDose software.

5.2 Device Comparison Table

The following table compares the BeamDose software with the predicate devices regarding to their performance data: These properties are software functions and no further acceptance criteria can be provided.

The predicate device has a larger range of functions than the subject device. Therefore, only the relevant functions which are implemented in the BeamDose software are considered.

Manufacturer	**PTW Freiburg**	**Standard Imaging**
Product name	**BeamDose software**	**DoseView software (part of DoseView 3D)**
Perform detector positioning in water phantom	Yes	Yes
Enter detector settings	Yes	Yes
Set electrometer settings • Bias (HV) • Range • Measurement mode	Yes	Yes
Perform zero adjustment	Yes	Yes
Enter correction factors	Yes	No
Enter temperature & air pressure	Yes	Yes
Readout electrometer	Yes	Yes
Control a 1D or 3D water phantom	Yes	Yes
Export data to a .csv file	Yes	Yes

Both, the BeamDose software and the predicate device provide the same functions relevant to the intended use of BeamDose which proves substantial equivalence with the predicate device.

6 Performance Data

The following performance data in combination with the stated electrometer were provided in support of substantial equivalence:

The BeamDose software was tested to evaluate and verify that it meets the required performance specifications which are defined in the product standard IEC 60731:2011 (Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy) which is specifically for reference class dosimeter systems and which were performed together with the respective electrometers.

Measuring specifications according to IEC 60731 for BEAMSCAN electrometer:

	BEAMSCAN	**Reference**
Ranges		IEC 60731, section 6.2.1
Charge		
LOW	20 pC … 22 µC	
MED	200 pC … 400µC	
HIGH	2 nC … 5 mC	
Current		
LOW	2 pA … 2.2 nA	
MED	20 pA … 40 nA	
HIGH	200 pA … 500 nA	
Zero drift	≤ ± 0.5 %	IEC 60731, section 6.3.1
Non-linearity	≤ ± 0.5 %	IEC 60731, section 6.3.2

Effect of influence quantities according to IEC 60731 for BEAMSCAN electrometer:

Influence quantity	**Nominal useful range of the influence quantity**	**Device characteristic**	**Max. change**	**Reference**
Range changing	all ranges	response	≤ ± 1 %	IEC 60731, section 6.3.4
Stabilization time	5 min	response	< ± 0.5 %	IEC 60731, section 6.2.5
Temperature	(+ 10 … + 40) °C	response zero drift	< ± 0.25 % ± 0.5 %	IEC 60731, section 6.4.6
Stray radiation	(0 … 0.2) mSv/h	zero drift zero shift	≤ ± 1 % ≤ ± 1 %	IEC 60731, section 6.3.8
Dose rate	± 2 pA … ± 2.2 nA	response	< ± 0.5 %	IEC 60731, section 6.4.3

Measuring specifications according to IEC 60731 for TANDEM and TANDEM^{XDR}:

	TANDEM	TANDEM^{XDR}	Reference
Ranges			IEC 60731, section 6.2.1
Charge			
LOW	50 pC … 10 µC	500 pC … 100 µC	
MED	500 pC … 100µC	5 nC … 1 mC	
HIGH	5 nC … 1 mC	50 nC … 10 mC	
Current			
LOW	5 pA … 1 nA	50 pA … 10 nA	
MED	50 pA … 10 nA	500 pA … 100 nA	
HIGH	500 pA … 100 nA	5 nA … 1 µA	
Zero drift	≤ ± 1 %	≤ ± 1 %	IEC 60731, section 6.3.1
Non-linearity	≤ ± 0.5 %	≤ ± 0.5%	IEC 60731, section 6.3.2

Effect of influence quantities according to IEC 60731 for TANDEM and TANDEM^{XDR}:

Influence quantity	Nominal useful range of the influence quantity	Device characteristic	Max. change	Reference
Range changing	all ranges	response	± (0.5 % + 1 digit) of display	IEC 60731, section 6.3.4
Stabilization time	5 min	response	± (0.5 % + 1 digit) of display	IEC 60731, section 6.2.5
Temperature	(+ 10 … + 40) °C	response zero drift	± (1 % + 1 digit) of display ± (1 % + 1 digit) (lower limit of measuring range)	IEC 60731, section 6.4.6
Stray radiation	(0 … 0.2) mSv/h	zero drift zero shift	± (1 % + 1 digit) (lower limit of measuring range) ± (1 % + 1 digit) (lower limit of measuring range)	IEC 60731, section 6.3.8
Dose rate	± 2 pA … ± 2.2 nA	response	< ± 0.5 %	IEC 60731, section 6.4.3

Measuring specifications and effect of influence quantities according to IEC 60731 for MULTIDOS, UNIDOS E, UNIDOS webline, UNIDOS Tango, and UNIDOS Romeo are similar and stated in their respective IFUs in the section “Technical Specifications”.

The device passed verification and validation testing and was deemed safe and effective for its intended use. Since both, the subject and the predicate device claim to be compliant to this standard, fulfilment of the standard requirements for the subject device proves to be substantially equivalent to the predicate device. Based on results of this testing the device was found to have a safety and effectiveness profile similar to the predicate device, supporting the claim of substantial equivalence.

7 Summary

The comparison of the indications for use, the technological characteristics, the performance, safety and effectiveness of the predicate devices and the subject device has shown that the BeamDose software is substantially equivalent to the predicate devices and that the application is as well or better. With respect to the use the device, no new questions of safety and effectiveness could be determined.