March 30, 2022

PTW-Freiburg Physikalisch-Technische-Werkstaetten Dr. Pychlau GmbH
℅ Sandor-Csaba Ats
Regulatory Affairs Manager
Loerracher Strasse 7
Freiburg, Baden-Württemberg 79102
GERMANY

Re: K213370
Trade/Device Name: VERIQA
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: February 14, 2021
Received: February 28, 2022

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,

Julie M. Sullivan, Ph.D.
Assistant Director
Nuclear Medicine and Radiation Therapy Branch
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213370

Device Name
VERIQA (S07031)

Indications for Use *(Describe)*

VERIQA is a software package for display, evaluation and digital processing of medical image data sets and treatment plans in radiation oncology.

VERIQA software is a tool for evaluation and data management of digital medical images and treatment plan information. It supports the medical imaging modalities CT, MR, PET according to the ACR/NEMA DICOM 3.0 standard and other modalities. VERIQA supports the following applications:

a) Receiving, transmitting, storing, retrieving, display, and processing of medical images and DICOM objects.
b) Creating, displaying and printing of reports containing medical images.
c) Image registration, fusion display, and review of medical images for treatment evaluation and treatment planning.
d) Localization and definition of structures such as tumors and normal tissue in medical image sets.
e) Creation, transfer, and modification of contours and dose distributions for applications such as quantitative analysis, aiding adaptive radiation therapy, transferring contours and dose distributions to radiation treatment planning systems, and archiving contours and dose distributions for patient follow-up and management.
f) Secondary Monte Carlo dose calculation and evaluation for patient specific quality assurance.

VERIQA must not be used while a patient is present. VERIQA must not be used for treatment planning.

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.

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

1 Submitter's Information

Company Name: PTW-Freiburg Physikalisch-Technische-Werkstaetten Dr. Pychlau GmbH

Company Address: Loerracher Strasse 7
79115 Freiburg
Germany

Proprietary Name: VERIQA (S07031)

Common Name: Secondary check QA software

510(k) number: K213370

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

2 Predicate Device Information

Proprietary Name: SUNCHECK
Common Name: Secondary check QA software
510(k) number: K170307
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: Sun Nuclear Corporation
Submitted: October 25, 2017

Proprietary Name: Mirada RTx
Common Name/s: RTx, RT Server, RTx Server, Workflow Box
510(k) number: K130393
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Classification Name: System, Image Processing, Radiological
Product code: IYE
Device class: Class II
Manufacturer: Mirada Medical Ltd
Submitted: March 20, 2013

3 Device Description

Software for viewing and analyzing of DICOM and DICOM RT data as well as for contouring of these data for radiation therapy. All the relevant data, including image data sets and treatment plans, can be imported into VERIQA. The software enables interactive viewing of these data in 2D/3D/4D and evaluation of the treatment plans with secondary Monte Carlo 3D dose calculation. The user can register images and process RT Dose, RT Plan, and RT Structure objects. Results can be saved in the DICOM RT format for use by other systems for radiation treatment planning purposes.

4 Intended Use Statement

VERIQA is a software package for display, evaluation and digital processing of medical image data sets and treatment plans in radiation oncology.

4.1 Indications

VERIQA software is a tool for evaluation and data management of digital medical images and treatment plan information. It supports the medical imaging modalities CT, MR, PET according to the ACR/NEMA DICOM 3.0 standard and other modalities.

VERIQA supports the following applications:

RT View and RT Evaluate:

a) Receiving, transmitting, storing, retrieving, display, and processing of medical images and DICOM objects.

b) Creating, displaying and printing of reports containing medical images.

c) Localization and definition of structures such as tumors and normal tissue in medical image sets.

d) Image registration, fusion display, and view of medical images for treatment plan valuation.

e) Creation, transfer, and modification of contours and dose distributions for applications such as quantitative analysis, aiding adaptive radiation therapy, transferring contours and dose distributions to radiation treatment planning systems, and archiving contours and dose distributions for patient follow-up and management.

RT MonteCarlo 3D:

f) Secondary Monte Carlo dose calculation and evaluation for patient specific quality assurance.

4.2 Contraindications

VERIQA must not be used while a patient is present. VERIQA must not be used for treatment planning.

4.3 Intended User

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

The primary technologic characteristic of VERIQA can be broken up into 3 modules of functionality.

a) The usage of three-dimensional imaging information and beam intensity information in DICOM-RT format to compute a dose distribution (also in DICOM-RT format) and a comparison of this independent calculation to the TPS dose distribution.

b) Visualization and storage of CT/MR and PET-CT images, structure sets and dose distributions in DICOM-RT format.

c) Contouring and image registration on the base of CT/MR images.

These technological characteristics are believed to be substantially equivalent to the predicate devices as seen in the below table.

5.2 Device Comparison Table

Manufacturer	**PTW Freiburg**	**Sun Nuclear**	**MIRADA MEDICAL**
Product name	**VERIQA**	**SunCHECK**	**MIRADA RTx**
510(k) number	K213370	K170307	K130393
Secondary dose calculation based on DICOM data from TPS	Yes, for conventional Elekta and Varian linacs.	Yes for conventional Elekta and Varian linacs and Accuray Tomotherapy.	No
Monte Carlo based dose calculation	Yes, for conventional Elekta and Varian linacs.	Yes, for Accuray Tomotherapy.	No
Visualization of CT, dose and structures	Yes visualization in RT viewer: VERIQA RT View	Yes Visualization in web-based slice viewer.	Yes
Support of CT, MR and PET according DICOM 3.0 standard	Yes VERIQA RT View	No	Yes
Calculation of 3D-gamma distribution	Yes	Yes	No
Visualization of 3D-gamma distribution	Yes visualization in RT viewer: VERIQA RT View	Yes Visualization in web-based slice viewer.	No
Calculation of dose-volume-histograms	Yes	Yes	No
Visualization of dose-volume-histogram	Yes	Yes	No
Image registration	Yes VERIQA RT Evaluate	No	Yes
Fusion display	Yes VERIQA RT View	No	Yes

Manufacturer	PTW Freiburg	Sun Nuclear	MIRADA MEDICAL
Product name	**VERIQA**	**SunCHECK**	**MIRADA RTx**
Localization and definition of structures	Yes, VERIQA RT Evaluate	No	Yes
Creation, transfer and modification of contours	Yes, VERIQA RT Evaluate	No	Yes
Automated processing of secondary checks	Yes	Yes	No
Template based evaluation	Yes	Yes	No
Automatic notification	Yes, Email notification	Yes Email notification and via notification center (software internal)	No
Alert system	Yes, Colour coded (red: failed, orange: warning, green: passed)	Yes Colour coded (red: failed, green: passed)	No
Digital evaluation approval and reject	Yes	Yes	No
Generation of PDF Report	Yes	Yes	No
Visualization of DICOM RT Plans	Yes, visualization in RT viewer: VERIQA RT View	Yes, Visualization in web-based slice viewer.	Yes
Modular software platform	Yes	Yes	No

6 Performance Data

Software verification and validation testing results were conducted and submitted according to appropriate bench testing methods.

It was demonstrated that VERIQA fulfils the design specification and its intended use, and that it is equivalent to the predicate devices.

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 VERIQA software is as safe and effective as 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.