April 15, 2026

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

Re: K252258
Trade/Device Name: VERIQA RT EPID 3D
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: July 18, 2025
Received: July 21, 2025

Dear Ats Sandor-Csaba:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252258

Please provide the device trade name(s).

VERIQA RT EPID 3D

Please provide your Indications for Use below.

Software for quality assurance of ionizing radiation emitted by diagnostic imaging devices or radiotherapy devices.

VERIQA RT EPID 3D is a software to assist the user in detecting errors related to
– treatment planning,
– plan delivery by the treatment machine,
– changes in the patient anatomy, and/or patient setup deviations.

VERIQA RT EPID 3D must not be used to modify a patient´s treatment plan based exclusively on the results from VERIQA RT EPID 3D. VERIQA RT EPID 3D must not be used for treatment planning.

The clinical user of VERIQA RT EPID 3D is the medical physicist. Transport tasks are performed by the carrier. PTW service staff is responsible for service tasks.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary – VERIQA RT EPID 3D

Submitted in accordance with 21 CFR 807.92

Date prepared: 2026-04-12

1 Submitter's Information

Company Name:	PTW-Freiburg Physikalisch-Technische-Werkstaetten Dr. Pychlau GmbH
Company Address:	Loerracher Strasse 7 79115 Freiburg Germany
510(k) Number:	K252258

2 Device Name and Classification

Proprietary Name:	VERIQA RT EPID 3D
Common Name:	Quality Assurance for Patient Radiation Treatment
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

3 Predicate Device

Proprietary Name:	PerFRACTION
Common Name:	Quality Assurance for Patient Radiation Treatment
510(k) number:	K141800
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:	June 30, 2014

4 Device Description

4.1 Introduction

VERIQA is a software package including among others the software module VERIQA RT EPID 3D.

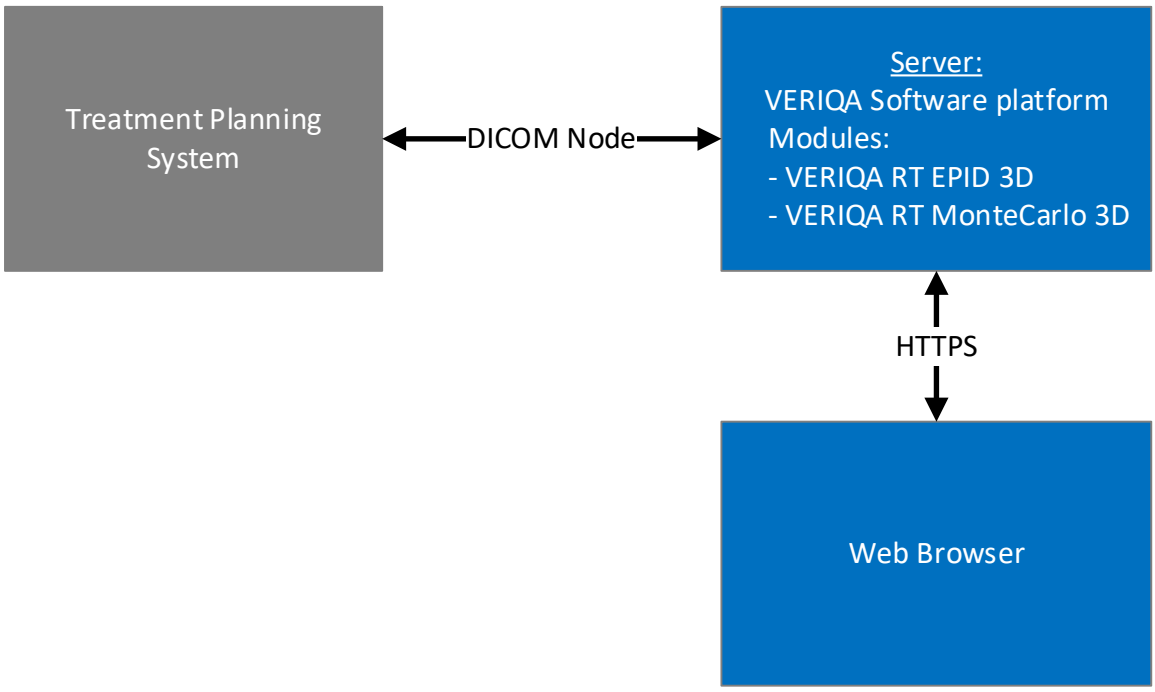
VERIQA RT EPID 3D is enabling 3D dose reconstruction in the patient anatomy based on acquired EPID images. If EPID images are acquired without the patient in the beam, RT EPID 3D will use the images to reconstruct a 3D dose distribution in a virtual patient for pre-treatment patient-specific QA. If EPID images are acquired during patient treatment, i.e. behind the treated patient, the images are used for *in vivo* dose reconstruction enabling the detection of patient-related errors, such as anatomical changes or mispositioning.

VERIQA RT EPID 3D is a server-based solution which can be accessed via a web-browser of any client computer in the same network.

VERIQA RT EPID 3D processes medical imaging information and related data and performs an automatic comparison between the reference and recalculated dose. This evaluation, often referred to as secondary check, is a method used by medical physicist as part of the patient-specific quality assurance measures.

4.2 System overview

VERIQA RT EPID 3D is installed on a server and can be accessed via a web-browser. The data transfer between treatment planning systems and VERIQA RT EPID 3D is realized via DICOM nodes.



(Only VERIQA RT EPID 3D is part of this 510(k) submission)

5 Intended Use Statement

VERIQA is a software for quality assurance of ionizing radiation emitted by diagnostic imaging devices or radiotherapy devices.

5.1 Device Description

VERIQA RT EPID 3D is a software for performing and evaluating a 3D dose calculation based on EPID images acquired before, after, and during patient treatment. VERIQA RT EPID 3D automatically processes DICOM RT data and EPID image data and performs a dose calculation and an evaluation based on DVH criteria and 3D gamma criteria.

The user can set dose calculation parameters and evaluation criteria individually. Evaluation results can be viewed, documented, and exported.

5.2 Operating Principle

VERIQA RT EPID 3D is based on a central server architecture. VERIQA RT EPID 3D can receive treatment plans from a treatment planning system via DICOM protocol. When treatment plans are transmitted to the central server, VERIQA RT EPID 3D automatically retrieves EPID image data and assigns it to the respective treatment plan.

Based on this, the 3D dose distribution in the patient anatomy is automatically calculated using a direct back- projection method and is evaluated against the planned patient dose. The results can be accessed via a web browser and/or viewed in a generated report.

5.3 Applications

VERIQA RT EPID 3D is a software to assist the user in detecting errors related to

- treatment planning,
- plan delivery by the treatment machine,
- changes in the patient anatomy, and/or patient setup deviations.

5.4 Exclusions

VERIQA RT EPID 3D must not be used to modify a patient´s treatment plan based exclusively on the results from VERIQA RT EPID 3D.

VERIQA RT EPID 3D must not be used for treatment planning.

5.5 Indications with Patient Population

VERIQA RT EPID 3D can be used for quality assurance in the delivery of radiation therapy for patients of any gender and age.

5.6 Contraindications

There are no contraindications for this product.

5.7 Intended User

The clinical user of VERIQA RT EPID 3D is the medical physicist. Transport tasks are performed by the carrier. PTW service staff is responsible for service tasks.

5.8 Intended Clinical Benefit

Performance:

VERIQA RT EPID 3D is used as a verification tool for the delivery of radiation therapy. VERIQA RT EPID 3D assists the medical physicist in identifying potential irradiation errors by means of dosimetric differences between the planned and the delivered dose.

Safety:

VERIQA RT EPID 3D offers medical physicists a control measure that assists them in verifying the correct dose delivery and provides an additional level of treatment safety. This gives medical physicists greater confidence, especially if complex irradiation techniques are employed. Hereby the clinical safety of the patient is increased.

6 Indications for Use (IFU)

Software for quality assurance of ionizing radiation emitted by diagnostic imaging devices or Radiotherapy devices. VERIQA RT EPID 3D is a software to assist the user in detecting errors related to

- – treatment planning,
- – plan delivery by the treatment machine,
- – changes in the patient anatomy, and/or patient setup deviations.

VERIQA RT EPID 3D must not be used to modify a patient´s treatment plan based exclusively on the results from VERIQA RT EPID 3D. VERIQA RT EPID 3D must not be used for treatment planning.

The clinical user of VERIQA RT EPID 3D is the medical physicist. Transport tasks are performed by the carrier. PTW service staff is responsible for service tasks.

7 Substantial Equivalence

7.1 Technological Characteristics

The subject device VERIQA RT EPID 3D (K252258) and the predicate device PerFRACTION (K141800) share the same intended use, namely EPID-based patient-specific quality assurance for both pre-treatment and in-vivo dosimetry. Although the devices employ different algorithmic approaches — VERIQA RT EPID 3D uses a clinically validated direct back-projection algorithm, whereas PerFRACTION utilizes a forward-calculation method — this difference does not raise new questions of safety or effectiveness. Consistent with FDA's substantial-equivalence principles, technological differences are acceptable provided they do not introduce new safety/effectiveness concerns.

Published evidence and internal performance data demonstrate that both algorithmic approaches exhibit comparable error-detection capabilities for clinically relevant delivery deviations. The back-projection method enables additional analytical functionality (3D patient dose reconstruction, 3D gamma distribution, DVH metrics); however, these features represent enhancements in analytical depth rather than a change in intended use or clinical principles of operation. They do not modify the clinical workflow nor introduce new hazards beyond those already present in EPID-based QA approaches.

7.2 Device Comparison Table

Manufacturer	**PTW Freiburg**	**Sun Nuclear**
Product name	**VERIQA RT EPID 3D**	**PerFraction**
510(k) number	K252258	K141800
Intended Use	Software for quality assurance of ionizing radiation emitted by diagnostic imaging devices or Radiotherapy devices. VERIQA RT EPID 3D is a software to assist the user in detecting errors related to treatment planning, plan delivery by the treatment machine, changes in the patient anatomy, and/or patient setup deviations. VERIQA RT EPID 3D must not be used to modify a patient´s treatment plan based exclusively on the results from VERIQA RT EPID 3D. VERIQA RT EPID 3D must not be used for treatment planning.	PerFRACTION is intended to allow for the detection of errors that can occur in the delivery of a patient's radiation therapy treatment. PerFRACTION allows for the comparison of the cumulative exit image(s) for one treatment fraction to the cumulative exit image(s) for another treatment fraction, thus providing a consistency check on the delivery of the treatment fraction.
Intended Use Comparison	Similar to predicate device: Both devices are software-only QA tools intended to assist users in detecting radiotherapy delivery-related errors through analysis of treatment imaging data, without controlling treatment, modifying the treatment plan, or being used as the sole basis for clinical decisions.	---
Pre-treatment and in vivo EPID dosimetry	Yes	Yes
3D patient dose reconstruction based on back-projection EPID dosimetry	Yes, using direct back-projection algorithm	No, using a forward calculation algorithm
Visualization of CT, dose and structures	Yes visualization in RT viewer	Yes Visualization in web-based slice viewer.
Calculation of 3D-gamma distribution	Yes	Yes
Visualization of 3D-gamma distribution	Yes visualization in RT viewer	Yes Visualization in web-based slice viewer.
Calculation of dose-volume-histograms	Yes	Yes
Visualization of dose-volume-histogram	Yes	Yes

Manufacturer	PTW Freiburg	Sun Nuclear
Product name	**VERIQA RT EPID 3D**	**PerFraction**
Automated processing of evaluations	Yes	Yes
Template based evaluation	Yes	Yes
Automatic notification	Yes, Email notification	Yes, Email notification and via notification center (software internal)
Alert system	Yes, Colour coded (red: failed, orange: warning, green: passed)	Yes Colour coded (red: failed, green: passed)
Digital evaluation approval and reject	Yes	Yes
Generation of PDF Report	Yes	Yes
Visualization of DICOM RT Plans	Yes, visualization in RT viewer: VERIQA RT View	Yes, Visualization in web-based slice viewer.
Modular software platform	Yes	Yes

7.3 SE Conclusion

Given the identical intended use, the comparable detection performance, and the absence of any new questions of safety or effectiveness, the forward-calculation algorithm of the predicate device constitutes an appropriate technological basis for substantial equivalence. Therefore, PerFRACTION is suitable as a predicate device for VERIQA RT EPID 3D.

8 Non-clinical Performance Testing

The non-clinical performance of VERIQA RT EPID 3D was evaluated through a series of software verification and validation and algorithm performance tests to support a determination of substantial equivalence.

The following non-clinical tests were conducted:

- Software verification and validation testing to confirm that the software performs according to its design specifications and intended use.
- Algorithm performance testing to verify the accuracy and robustness of the EPID-based 3D dose reconstruction and evaluation functions.
- Performance evaluation of dose calculation and comparison workflows, including assessment of dose-volume histogram (DVH) metrics and three-dimensional gamma analysis.

- Data integrity and workflow testing to confirm correct processing of DICOM RT data and EPID image data within the intended clinical quality assurance workflow.

The non-clinical testing demonstrated that VERIQA RT EPID 3D reliably performs dose reconstruction, evaluation, and error-detection functions consistent with its intended quality assurance purpose. The test results showed that the performance of the subject device is comparable to that of the predicate device and does not raise any new questions of safety or effectiveness. These results support the conclusion that VERIQA RT EPID 3D performs as intended and is substantially equivalent to the predicate device.

9 Clinical Testing

Clinical testing was not required because the device supports QA processes and does not determine or modify patient treatment.

10 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 RT EPID 3D software 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, no new questions of safety and effectiveness could be determined.