DoseOptics LLC
℅ Farzeen Christie
Consultant
16 Cavendish Court
LEBANON NH 03766

December 11, 2020

Re: K200940
Trade/Device Name: BeamSite™ System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: November 6, 2020
Received: November 9, 2020

Dear Farzeen Christie:

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,

For

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)*
K200940

Device Name
BeamSite™ System

Indications for Use *(Describe)*
The BeamSite™ System is intended to be used only with photon external beam radiotherapy during treatment to acquire and visualize the shape of the treatment radiation beam relative to surface anatomical landmarks on the patient, anywhere in the body where radiation treatment is indicated. BeamSite is used by radiotherapy professionals in appropriate hospital and freestanding radiation therapy environments.

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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5. 510(k) SUMMARY

K200940

Revised 12/04/2020

5.1. SUBMITTER

DoseOptics LLC
16 Cavendish Court
Lebanon, NH 03766
Phone: (603) 643-5177

Contact Person:	Farzeen Christie
Email:	farzeen@doseoptics.com
Date Prepared:	April 7, 2020

5.2. SUBJECT DEVICE

Device Trade Name:	BeamSite™ System
Device Common Name:	Radiotherapy Visualization System
Classification Name:	Medical Charged Particle Radiation Therapy System (21 CFR 892.5050)
Regulatory Class:	II
Product Code:	IYE
Panel:	Radiology

5.3. PREDICATE DEVICE

PortalVision™ Advanced Imaging Device, K091209 manufactured by Varian Medical Systems.

5.4. DEVICE DESCRIPTION

BeamSite™ is a system that enables real-time visualization of the treatment beam on a patient during radiotherapy. It is an optically based system that is non-patient contacting and produces no radiation. BeamSite captures images of Cherenkov light emitted from the patient's skin during radiotherapy to provide an optical map of the beam on the patient. The BeamSite system consists of a camera, workstation with pre-installed BeamSite software and a monitor to be used by clinical radiotherapy teams to visually observe the treatment, as it happens, and review after the treatment, if necessary.

The BeamSite system is designed to be used as a fixed mounted camera having a field of view of the treatment area, to routinely image patient treatments with minimal impact to the clinical workflow. The video images produced are intended to provide additional information about the treatment for the clinical team by displaying the beam size and shape on the patient during treatment. The images produced will provide real-time, direct visual indication that the beam is on, that it is impacting the patient at the intended treatment surface, provides visual feedback regarding the patient's movement relative to the beam, and that surfaces of the body not intended for treatment remain outside the beam path. BeamSite is to be used as a visualization tool. Therapeutic decisions should not be made solely based on the images acquired from this device. However, the images will provide a simple and intuitive means to visually monitor radiation therapy on a routine basis.

5.5. INDICATIONS FOR USE / INTENDED USE

The BeamSite System is intended to be used only with photon external beam radiotherapy during treatment to acquire and visualize the shape of the treatment radiation beam relative to surface anatomical landmarks on the patient, anywhere in the body where radiation treatment is indicated. BeamSite is used by radiotherapy professionals in appropriate hospital and freestanding radiation therapy environments.

5.6. COMPARISON TO PREDICATE DEVICE

The Predicate Device for the BeamSite System is PortalVision Advanced Imaging Device, K091209, manufactured by Varian Medical Systems.

The PortalVision Advanced Imaging Device is indicated to acquire images of anatomical landmarks, fiducial markers, the shape of the treatment beam and dosimetric signals to guide the delivery of radiation anywhere in the body where radiation treatment is indicated.

Whereas, the BeamSite System is indicated for a subset of this indication, namely, it is intended to be used during treatment to acquire and visualize the shape of the treatment radiation beam relative to

surface anatomical landmarks on the patient, anywhere in the body where radiation treatment is indicated.

Both devices require the ionizing radiation beam to be exposing the patient at the time they acquire their images.

The BeamSite System is not a substitute for the predicate but provides additional information to the user when compared to the PortalVision Advanced Imaging Device in that it presents a visual image of the actual shape of the irradiation field on the patient in relation to a visual image of the patient anatomical surface in and around the irradiation field.

Both devices require image analysis and presentation software to display images on a monitor to the user for further human analysis and decision making.

Characteristic	**Predicate Device:** **PortalVision Advanced Imaging Device (K091209)**	**Subject Device:** **DoseOptics BeamSite System**
Intended Use	The PortalVision Advanced Imaging device is used to acquire images of anatomical landmarks, fiducial markers, the shape of the treatment beam and dosimetric signals to guide the delivery of radiation anywhere in the body where radiation treatment is indicated.	The BeamSite System is intended to be used only with photon external beam radiotherapy during treatment to acquire and visualize the shape of the treatment radiation beam relative to surface anatomical landmarks on the patient, anywhere in the body where radiation treatment is indicated. BeamSite is used by radiotherapy professionals in appropriate hospital and freestanding radiation therapy environments.

Characteristic	**Predicate Device:** **PortalVision Advanced Imaging Device (K091209)**	**Subject Device:** **DoseOptics BeamSite System**
Indications for Use	The PortalVision Advanced Imaging device is used to acquire images of anatomical landmarks, fiducial markers, the shape of the treatment beam and dosimetric signals to guide the delivery of radiation anywhere in the body where radiation treatment is indicated.	The BeamSite System is intended to be used only with photon external beam radiotherapy during treatment to acquire and visualize the shape of the treatment radiation beam relative to surface anatomical landmarks on the patient, anywhere in the body where radiation treatment is indicated. BeamSite is used by radiotherapy professionals in appropriate hospital and freestanding radiation therapy environments.
Type of Use	Prescription Use	Same
Device Role and System Output	Serves as an accessory to LINAC	Same
Target Population	Any individual (Adult or Child undergoing radiotherapy)	Same
Energy Delivered to the Patient	No energy delivered to the patient by the device	Same
Use Environment	Radiation image detection subsystem is inside the treatment room and the PC Workstation to view the images is outside the treatment room in therapist control area	Same
Beam Energies Used	All therapeutic X-Ray energies from the linac	Same

Characteristic	**Predicate Device: PortalVision Advanced Imaging Device (K091209)**	**Subject Device: DoseOptics BeamSite System**
	radiation beam can be imaged	
Viewing Method	Display of image is on a computer monitor using custom software application installed on a Windows PC	Same
Supporting System Components	PC Work Station and Cables between treatment room and therapist control area	Same
Field Size of Image	Radiation Beam can be viewed within the 40cm X 30cm detector area of the Image Detection Unit.	40cm X 40cm
Software Features	Image Acquisition, Review, and Storage are possible by the computer and software.	Same
Biocompatibility	No contact with patient or clinical staff in the treatment room.	Same
Image Source	X-ray treatment beam	Same
Image Acquisition Geometry	Images of the exit treatment beam field size and shape.	Images of the treatment beam field size and shape impinging on the patient anatomy.
Image Detection	Flat-panel Amorphous Silicon detector	X-rays interact with tissue on and near the surface of patient's anatomy and produce concomitant light output by the Cherenkov emission process. The light is imaged by an intensified camera system with a Complementary Metal Oxide Semiconductor (CMOS) sensor.

Characteristic	**Predicate Device:** PortalVision Advanced Imaging Device (K091209)	**Subject Device:** DoseOptics BeamSite System
Image patient surface anatomy	Not possible	Patient surface anatomy is visualized between treatment beam pulses utilizing ambient light.
Image Processing	Proprietary software performs image processing and displays images on the monitor.	Image acquisition electronics performs imaging in sync and out of sync with the treatment beam pulses. Software performs image processing and displays images on the monitor.

Although PortalVision Advanced Imaging Device and the BeamSite System acquire their images using different technologies, both are accessories to a medical linear accelerator, both require an active ionizing radiation beam and both do acquire and visualize the shape of the treatment radiation beam relative to surface anatomical landmarks on the patient, anywhere in the body where radiation treatment is indicated.

For both devices, the patient receives their radiation therapy whether or not either device is in use. Neither device interacts directly with the patient, but both utilize information present in the treatment beam. Since the BeamSite System is not a substitute for the PortalVision Advanced Imaging Device, but provides new visual information to the user, the technological differences do not raise new or different concerns of safety and effectiveness.

5.7. PERFORMANCE TESTING SUMMARY (NON-CLINICAL)

The following performance data are provided in support of the substantial equivalence determination.

- BeamSite functional verification testing (system, software and firmware)
- Accelerated age testing to support expected service life claim for the BeamSite Camera
- Electrical Safety Evaluation as per IEC 60601-1:2005 / (R) 2012 and A1: 2012
- Electromagnetic Compatibility testing as per IEC 60601-1-2: 2014
- Software Verification and Validation as per IEC 62304:2006 / A1: 2016
- Usability Testing as per IEC 60601-1-6 Edition 3.1 2013-10 and IEC 62366-1: 2015

5.8. CONCLUSIONS

Based on performance testing of BeamSite and the evaluation of predicate characteristics, we claim the BeamSite System to be substantially equivalent to existing legally marketed device, PortalVision (K#091209).