DoseOptics LLC
℅ Farzeen Christie
Consultant
16 Cavendish Ct.
LEBANON NH 03766

September 15, 2021

Re: K212606
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: August 16, 2021
Received: August 17, 2021

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,

Julie Sullivan -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212606

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.

5. 510(k) SUMMARY

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:	August 16 2021

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

BeamSite System, K200940 manufactured by DoseOptics LLC.

5.4. DEVICE DESCRIPTION

BeamSite™ is a camera system that enables live 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. When the treatment beam is on, BeamSite captures images of Cherenkov light emitted from the patient's skin during radiotherapy to provide an optical map of the treatment beam on the patient. When the treatment beam is off, the system provided continuous background images of the treatment area under ambient light illumination. The BeamSite system consists of a camera, a workstation with pre-installed BeamSite software, and a monitor to be used by clinical radiotherapy teams to a) visually observe the patient and the Cherenkov light emitted from irradiated surface anatomy, and b) review the treatment images, 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 size and shape of the beam on the patient during treatment. The images produced will provide real-time, direct visual indication:

- that the beam is on;
- that the beam is impacting the patient at the intended treatment surface;
- of visible patient's movement relative to the beam; and
- that surfaces of the body, that are not intended for treatment, remain outside the beam path.

In addition, in the modified device, the background images of the treatment area are now continuously displayed before and after treatment, providing an "always on" imaging experience preferred by the therapists. However, like with the original device, only the images acquired during the actual beam irradiation are stored for offline review.

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

Characteristic	**Predicate Device:** DoseOptics BeamSite System (K200940)	**Subject Device:** DoseOptics BeamSite System, V 1.5
Intended Use / Indications for 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.	Same
Type of Use	Prescription Use	Same
Device Role and System Output	Serves as an accessory to LINAC	Same
Target Population	Any individual (Adult of 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 radiation beam can be imaged	Same
Viewing Method	Display of image is on a computer monitor using	Same

Characteristic	**Predicate Device:** DoseOptics BeamSite System (K200940)	**Subject Device:** DoseOptics BeamSite System, V 1.5
	custom software application installed on a Windows PC	
Supporting System Components	PC Workstation and Cables between treatment room and therapist control area	Same
Field Size of Image	40cm X 40cm	Same
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
Types of Images Acquired	Images of the treatment beam field size and shape impinging on the patient anatomy.	Images of the treatment beam field size and shape impinging on the patient anatomy during treatment. Additional Feature: video feed of the treatment area before and after treatment.
Beam Image Detection	X-rays interact with tissue on and near the surface of the patient's anatomy and produce visible light by the Cherenkov emission process. The light is imaged by an intensified camera system with a Complementary Metal Oxide Semiconductor (CMOS) sensor.	Same
Patient Surface Anatomy Imaging	Patient surface anatomy is visualized between treatment beam pulses utilizing ambient light.	Same

Characteristic	**Predicate Device:** DoseOptics BeamSite System (K200940)	**Subject Device:** DoseOptics BeamSite System, V 1.5
Image Processing	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.	Same
Imaging Modes	User Interface (UI) displays "waiting for beam" message until the treatment beam comes online and transitions to displaying and recording images of the treatment beam intersecting the patient anatomy when the treatment beam comes on.	UI displays ambient light images of the treatment area continuously. UI displays and records images of the treatment beam intersecting the patient anatomy when the treatment beam comes on.

The Predicate Device for the BeamSite System V 1.5 is the previously cleared BeamSite (K200940), manufactured by DoseOptics LLC. The indications for use for the proposed device is identical to the indications for use of the cleared device.

However, the proposed device differs in few technological characteristics from the cleared device. The proposed device has an additional feature of continuously displaying ambient light background images of the treatment area to the user even when the beam is not on, further referred to as "always on" mode. This way, a continuous video feedback is provided to the user. This live video is not recorded. The feature of displaying Cherenkov images, recording and providing playback options is identical to the predicate device. There is no change to the main objective / intended use of the device.

In addition to the technological characteristic change of having the always on capability, a few device components have been changed in the proposed device. These changes and technological differences do not raise new or different concerns of safety and effectiveness. The performance testing conducted on the predicate device were repeated

on the proposed modified device to show that the differences did not affect the performance and specifications of the proposed device.

5.7. PERFORMANCE TESTING SUMMARY (NON-CLINICAL)

The following performance testing was repeated on the proposed device 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 modified BeamSite and the evaluation of predicate characteristics, we claim that the modified BeamSite System (V 1.5) to be substantially equivalent to existing legally marketed device, BeamSite (K#200940), and that the differences in technological characteristics do not raise different questions of safety and efficacy.