VHA Dean
% Laura Gilmour
Principal Consultant
LG Strategies, LLC
3903 S. Congress Ave #3930
AUSTIN TX 78704

November 4, 2022

Re: K222639
Trade/Device Name: VHA Radiotherapy Bolus
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: Class II
Product Code: IXI
Dated: August 31, 2022
Received: September 1, 2022

Dear Laura Gilmour:

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,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2022.11.04 15:35:42 -04'00'

for

Daniel M. Krainak, Ph.D.
Assistant Director
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)*
K222639

Device Name
VHA Radiotherapy Bolus

Indications for Use *(Describe)*

The VHA Radiotherapy Bolus product is a device that will be placed on the skin of a patient as a radiotherapy accessory intended to help control the radiation dose received by the patient. VHA Radiotherapy Boluses are designed by radiation therapy professionals for a unique patient and are intended to modify the shape of a beam from a radiation therapy source. The VHA Radiotherapy Bolus product must be verified and approved by the radiation therapy professional prior to use on a patient. The VHA Radiotherapy Bolus is intended for patients of all ages receiving radiotherapy treatment.

VHA Radiotherapy Bolus was evaluated using 6 MV photons and 9MeV electrons but has not been assessed for use with protons or at orthovoltage X-rays.

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.

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5. 510(k) Summary K222639

5.1 Applicant/Submitter

Company Name	VHA DEAN
Company Street Address	810 Vermont Avenue, NW
City	Washington
State	DC
Country	United States
Zip Code	20420

5.2 Contact Person

Full Name	Beth Ripley, MD, PhD
Job Title	Deputy Chief
Email	beth.ripley@va.gov

5.3 Correspondent Information

Full Name	Laura Gilmour
Job Title	Principal Consultant, Advanced Manufacturing and Regulatory Strategy
Phone	901-258-3629
Email	laura.gilmour@va.gov

5.4 Date of Preparation

Date of Preparation	October 25, 2022

5.5 Device Information

Table 5.1 Device Information

Trade Name	VHA Radiotherapy Bolus
Common or Usual Name	Patient specific radiotherapy bolus
Classification Name	Radiation therapy beam-shaping block
Classification Regulation	892.5710
Regulatory Class	Class II
Product Code	IXI

5.6 Predicate Device(s)

Table 5.2 Predicate Device(s)

Predicate Type	510(k) Number	Device Name	Manufacturer
Primary Device	K214093	VSP Bolus	3D Systems
Reference Device	K091911	Bolus Compensator	.decimal

The predicate devices have not been subject to a design-related recall.

5.7 Device Description

Boluses are used in external beam radiation therapy (EBRT) to change the depth of the radiation dose delivered, thereby overcoming the skin-sparing effect. Using clinical treatment planning software (TPS) and clinical expertise, a radiotherapy clinician designs the bolus to conform with the patient anatomy. The bolus is produced using additive manufacturing in a soft elastomeric material to conform to the patient's skin. The bolus is placed on the patient and verified for fit and acceptance to the clinical treatment plan prior to initiating treatment.

5.8 Intended Use/Indications for Use

The VHA Radiotherapy Bolus product is a device that will be placed on the skin of a patient as a radiotherapy accessory intended to help control the radiation dose received by the patient. VHA Radiotherapy Boluses are designed by radiation therapy professionals for a unique patient and are intended to modify the shape of a beam from a radiation therapy source. The VHA Radiotherapy Bolus product must be verified and approved by the radiation therapy professional prior to use on a patient. The VHA Radiotherapy Bolus is intended for patients of all ages receiving radiotherapy treatment.

VHA Radiotherapy Bolus was evaluated using 6 MV photons and 9MeV electrons but has not been assessed for use with protons or at orthovoltage X-rays.

5.9 Comparison of Technological Characteristics with Predicate

VHA DEAN believes that the VHA Radiotherapy Bolus is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has the same intended use and technological characteristics to the device cleared in K214093. Technological characteristics include identical manufacturing method, material, patient population and use environment as K214093. The reference device (K091911) and the subject device have the same input parameters. These technological characteristics have undergone testing to ensure the device is as safe and effective as the predicate (K214093).

A comparison of the technical characteristics between VHA Radiotherapy Bolus and the predicate device is provided in the following Comparison Table:

Table 5.3 Technical Characteristics Comparison Table

Specification/ Characteristic	Subject Device VHA Radiotherapy Bolus VHA DEAN K222639	Primary Predicate Device VSP® Bolus 3D Systems, Inc. K214093
Indications for Use	The VHA Radiotherapy Bolus product is a device that will be placed on the skin of a patient as a radiotherapy accessory intended to help control the radiation dose received by the patient. VHA Radiotherapy Boluses are designed by radiation therapy professionals for a unique patient and are intended to modify the shape of a beam from a radiation therapy source. The VHA Radiotherapy Bolus product must be verified and approved by the radiation therapy professional prior to use on a patient. The VHA Radiotherapy Bolus is intended for patients of all ages receiving radiotherapy treatment. VHA Radiotherapy Bolus was evaluated using 6 MV photons and 9MeV electrons but has not been assessed for use with protons or at orthovoltage X-rays	The 3D Systems VSP® Bolus product is a device that will be placed on the skin of a patient as a radiotherapy accessory intended to help control the radiation dose received by the patient. VSP Bolus is generated using input from radiation therapy professionals and medical imaging data to produce a bolus that is specific to the patient being treated. The VSP Bolus product is verified and approved by the radiation therapy professional prior to use on the patient, and is intended for patients of all ages receiving radiotherapy treatment. VSP Bolus was evaluated using 6 MV photons but has not been assessed for use with protons, electrons, or at orthovoltage X-rays.
Device Input Parameters	1. DICOM 2. The device is designed by the radiation therapy professional.	1. DICOM 2. Radiotherapy professional input (i.e. thickness, anatomical location)
Device Manufacturing Method	Additive Manufacturing (3D Printing)	Additive Manufacturing (3D Printing)
Device Material	VisiJet® M2E-BK70	VisiJet® M2E-BK70
Patient Contact Material Standards	Biocompatible for intact skin contact	Biocompatible for intact skin contact
Device Clinical Acceptance	Each VHA Radiotherapy Bolus must be verified and approved by the radiation therapy professional through a CT scan prior to the first treatment fraction.	Each VSP® Bolus must be verified and approved by the radiation therapy professional through a CT scan prior to the first treatment fraction.
Patient Population	Cancer patients requiring external beam radiotherapy.	Cancer patients requiring external beam radiotherapy.
Patient Population Anatomical Sites	Various	Various
Use Environment	Radiotherapy Clinic	Radiotherapy Clinic
Device Performance	Clinically oriented validation test cases were written and executed. The VHA Radiotherapy Bolus was deemed fit for clinical use by radiation therapy professionals.	Clinically oriented validation test cases were written and executed. VSP Bolus was deemed fit for clinical use by radiation therapy professionals.

5.10 Summary of Non-Clinical Testing

The following tests were performed to demonstrate safety based on current industry standards:

5.10.1 Performance Testing

Simulated use testing was completed for clinically relevant cases using both electron and photon radiation therapy. All acceptance criteria for performance testing were met.

5.10.2 Biocompatibility Testing

The VHA Radiotherapy Bolus has identical indications for use, identical material and manufacturing method, and an identical worst-case configuration and post processing conditions to the predicate device. Therefore, the subject device leveraged data on hand. All acceptance criteria for biocompatibility were met and the testing adequality addresses biocompatibility for the output devices and their intended use. Biocompatibility testing was in compliance to *ISO 10993-1 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process, ISO 10993-5 Biological evaluation of medical devices—Part 5: Tests for In Vitro cytotoxicity, and ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.*

5.11 Clinical Testing

No clinical data were provided in order to demonstrate substantial equivalence.

5.12 Conclusion

Based on the testing performed, including performance testing and biocompatibility testing, it can be concluded that the subject device does not raise any new issues of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the VHA Radiotherapy Bolus are assessed to be substantially equivalent to the predicate device.