3D Systems
% Benjamin Johnson
Vice President, Portfolio and Regulatory
5381 S Alkire Circle
LITTLETON CO 80127

March 30, 2022

Re: K214093
Trade/Device Name: VSP® Bolus
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: Class II
Product Code: IXI
Dated: March 3, 2022
Received: March 4, 2022

Dear Benjamin Johnson:

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,

Jessica Lamb, Ph.D.
Assistant 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.

Submission Number *(if known)*

K214093

Device Name

VSP Bolus

Indications for Use *(Describe)*

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.

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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Medical Modeling™

K214093

510(K) SUMMARY

1. INTRODUCTION

This document contains the 510(k) summary for VSP® Bolus. The content of this summary is based on the requirements of 21 CFR 807.92.

2. SUBMITTER

Name: 3D Systems, Inc.

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Littleton, CO 80127, USA
Phone: (720) 643-1001
Fax: (720) 643-1009

Official Contact: Benjamin Johnson
Vice President, Portfolio & Regulatory, Healthcare

Date Prepared: December 20th, 2021

3. DEVICE

Trade Name: VSP® Bolus

Common Name: Patient-specific Radiotherapy Bolus

Classification Name: Radiation therapy beam-shaping block

Classification: Class II, 21 CFR 892.5710

Product Code: IXI

4. PREDICATE DEVICES

Predicate device: BOLUS COMPENSATOR, .DECIMAL INC. (K091911)

5. DESCRIPTION OF THE DEVICE

Boluses are used in external beam radiation therapy (EBRT) to change the depth of the radiation dose delivery to overcome the skin-sparing effect. The bolus is generated in accordance with a clinical treatment plan. The patient-specific bolus conforms to the patient anatomy to reduces airgaps for complex patient contours. The bolus is produced with 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 accordance to the treatment plan prior to a radiation dose delivery to the patient.

6. INTENDED USE

The 3D Systems bolus product is placed on the skin of a patient with the intended use of helping control the dose received by that patient when undergoing radiation therapy treatment. The bolus will be manufactured according to the unique, patient-specific shape requested by a clinical customer. The 3D Systems bolus product is intended for patients of all ages requiring external beam radiotherapy, and is intended for prescription use only.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The intended use and technological characteristics of the subject device are either identical or substantially equivalent to the predicate device, differing only in the materials and manufacturing methods to produce the device. The potential impact on substantial equivalence of each technological difference was addressed by risk analysis and clinically oriented testing.

A comparison of the technical characteristics between VSP® Bolus and predicate device is provided in the following Comparison Table.

Predicate Comparison Table		
Attribute	**VSP® Bolus Subject Device**	**Bolus Compensator Predicate Device**
Indications for Use	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.	The Bolus Compensators are used by radiation therapy professionals for the treatment of cancer patients. They are designed by radiation therapy professionals for a unique patient and are intended to modify the shape of abeam from a radiation therapy source. Each Bolus Compensator must be validated and approved by the radiation therapy professional prior to use on a patient.
Device Input Parameters	1. DICOM 2. Radiotherapy professional input (i.e. thickness, anatomical location)	1. DICOM 2. The device is designed by the radiation therapy professional.
Manufacturing Method	Additive Manufacturing (3D Printing)	Subtractive Manufacturing (Machining)
Device Material	VisiJet® M2E-BK70	Deep Blue Wax
Patient Contact Materials	Biocompatible for intact skin contact.	"negligible irritation to skin at ambient temperatures"[1]
Device Clinical Acceptance	Each VSP® Bolus must be validated and approved by the radiation therapy professional through a CT scan prior to the first treatment fraction.	Each Bolus Compensator must be validated and approved by the radiation therapy professional to use on a patient.

Predicate Comparison Table		
Attribute	**VSP® Bolus Subject Device**	**Bolus Compensator Predicate Device**
Target Population	Cancer patients requiring external beam radiotherapy	Cancer Patients requiring external beam radiation therapy
Target Population Anatomical Sites	Various	Various
Use Environment	Radiotherapy Clinic	Radiotherapy Clinic
Performance	Clinically oriented validation test cases were written and executed. VSP Bolus was deemed fit for clinical use by radiation therapy professionals.	Clinically oriented validation test cases were written and executed in house .decimal personnel including Board Certified Medical Physicists where Bolus Compensators was deemed fit for clinical use.

1) Deep Blue Wax MSDS, QAF-312 Rev 071814

8. SUMMARY OF CLINICAL TESTING

Clinical testing was not performed as part of the development of this product. Clinical testing is not advantageous in demonstrating substantial equivalence, safety, or effectiveness of the device since testing can be performed such that no human subjects are exposed to risk.

9. SUMMARY OF PERFROMANCE TESTING

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

Biocompatibility Testing

The biocompatibility evaluation for the VSP Bolus was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medica Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Simulated Use Testing

Clinically relevant validation study was performed.

10. CONCLUSION

The VSP® Bolus has the same intended use and similar or substantially equivalent technological characteristics as the predicate. Minor differences in the technological characteristics do not raise new or different questions of safety and effectiveness.