July 10, 2018

3D Bolus, Inc.
% Peter Hickey
CEO
1344 Summer St
Suite 3015
HALIFAX B3H 0A8
CANADA

Re: K180289
Trade/Device Name: 3D Bolus Software
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: January 26, 2018
Received: February 1, 2018

Dear Mr. Hickey:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180289

Device Name
3D Bolus Software

Indications for Use *(Describe)*
3D Bolus Software is indicated for, and intended for use as, an accessory to a radiation therapy treatment planning system (TPS) to design patient-specific 3D-printable objects intended for use during external beam photon or electron radiation therapy, or brachytherapy.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

The following information is provided following the format of 21 CFR 807.92.

Submitter: 3D Bolus, Inc.
1344 Summer St, Suite 405
Halifax NS B3H 0A8
Canada

Contact Name: Peter Hickey, CEO
Phone: (902)-442-9091
Email: peter.hickey@3DBolus.com

Date Summary was prepared: January 17, 2017

Name of the Device:

Trade/Proprietary Name:	3D Bolus Software
Common or Usual Name:	Radiation therapy Treatment Planning System
Classification Name:	System, Planning, Radiation Therapy Treatment
Regulation:	21 CFR 892.5050
Class:	Class II
Product Code:	MUJ

Predicate Device: .decimal "p.d software (version 5.1)", K151369

Reference Device: Varian Medical Systems, Inc. "Eclipse Treatment Planning System", K172163

Description of Device:

The 3D Bolus Software is a device consisting of software that is used in conjunction with a radiation therapy treatment planning system (TPS) to produce a software file that can be used with a 3D printer to produce a customized, patient-specific bolus for electron or photon external beam radiation therapy or a customized, patient-specific surface brachytherapy mold. A radiation therapy bolus is used when treating uneven surface areas of a patient, such as at the nose or ears, to make up for missing tissue, or to provide build-up of dose to the skin surface. The use of a 3D printed bolus in post-mastectomy radiation therapy has been proven[1] to not only improve fit of the bolus, but also

[1] According to an Intra-patient study comparing 3D printed bolus versus standard vinyl gel sheet bolus for postmastectomy chest wall radiation therapy (James L. Robar, et. al. – December 24, 2017) https://www.sciencedirect.com/science/article/pii/S1879850017303843

reduces patient setup time by approximately 30% compared with standard vinyl gel sheet bolus, according to an intra-patient study comparing both methods. Additionally, the 3D Bolus Software designed bolus can modulate electron beam radiation therapy to produce a conformal high dose region around the tumor.

Files for three types of structures can be generated by the 3D Bolus Software and checked by the user on their TPS for correctness. When accepted by the user, the 3D Bolus Software will create a Stereolithography (STL) file for the user to print on a third-party 3D printer located within the facility.

Statement of Intended Use: 3D Bolus Software is indicated for, and intended for use as, an accessory to a radiation therapy treatment planning system (TPS) to design patient-specific 3D-printable objects intended for use during external beam photon or electron radiation therapy, or brachytherapy.

Statement of Indications For Use: 3D Bolus Software is indicated for, and intended for use as, an accessory to a radiation therapy treatment planning system (TPS) to design patient-specific 3D-printable objects intended for use during external beam photon or electron radiation therapy, or brachytherapy.

Summary of the Technological Characteristics:
3D Bolus Software has a similar Intended Use and Indications For Use as the predicate device. A comparison of the major technological characteristics is provided in the following Comparison Table.

PREDICATE COMPARISON TABLE		
ATTRIBUTE	**PREDICATE** **.decimal p.d software (v5.1)** **K151369**	**DEVICE** **3D Bolus Software (v1.2.2)**
Intended Use	The intended use of the p.d software is to aid radiation therapy professionals in the design, construction, and testing of radiotherapy beam modifying devices. The software is intended to interface with most major treatment planning systems	3D Bolus Software is indicated for, and intended for use as, an accessory to a radiation therapy treatment planning system (TPS) to design patient-specific 3D-printable objects intended for use during external beam photon or electron radiation

	and design devices that are compatible with most major radiotherapy linear accelerators and particle therapy delivery systems. And while the primary intent is for the software to design and measure devices that are manufactured by .decimal, this does not exclude, in some cases, the software being used with devices that are constructed on-site or by other vendors (with explicit permission from .decimal).	therapy, or brachytherapy.
Indications for Use	The p.d software is used by radiation therapy professionals to assist in the design, manufacturing, and quality assurance testing of various radiation therapy devices used for cancer patients. The p.d software performs three distinct, primary functions which each are described below. 1) The p.d software takes a design of a compensating filter from a Treatment Planning System and converts the Treatment Planning System compensator filter files into a .decimal file format. This file can then be electronically submitted to .decimal through the	3D Bolus Software is indicated for, and intended for use as, an accessory to a radiation therapy treatment planning system (TPS) to design patient-specific 3D-printable objects intended for use during external beam photon or electron radiation therapy, or brachytherapy.

	software, so that we can manufacture the device. 2) The p.d software can design a beam shaping and compensating filters based on Treatment Planning System and other user supplied data. The device designs for compensating filters will be transferred back into the Treatment Planning System for final dose verification before devices are ordered and used for patient treatment. 3) The p.d software can perform quality assurance testing of the physical characteristics of treatment devices using data from various types of scanned images, including computed tomography images.	
Target Population	Cancer patients requiring external beam radiotherapy	Any patient prescribed radiation therapy requiring an applicable accessory device.
Anatomical Site(s)	Various	Various
Use Environment	Radiation oncology clinical setting	Radiation oncology clinical setting
Product Material	Deep Blue Wax	Printed using Polylactic Acid (PLA) and Thermoplastic Polyurethane (TPU) filaments

Electron Product	Milled variable thickness bolus	3D printed variable thickness bolus
Photon Product	Milled uniform thickness bolus	3D printed uniform thickness bolus
Brachytherapy Product	None	3D printed brachytherapy mold with source trajectory tubes.
Patient Product Plan	From treatment planning system. p.d software modifies plan for milling at .decimal. Finished product is shipped to the treatment facility.	From treatment planning system. 3D Bolus software modifies plan for 3D printing within the treatment facility.
Communication with Treatment Planning System	DICOM file format, but other vendor specific or generic file formats are also utilized.	DICOM RT
Quality Assurance	Product designed by p.d software is checked for accuracy on the treatment planning system before being sent for milling at .decimal.	Product designed by 3D bolus software is checked for accuracy on the treatment planning system before printing by in-house 3D printer.
Biocompatibility	"Negligible irritation to skin at ambient temperatures." (From .decimal Deep Blue Wax MSDS)	It is recommended to place food-safe plastic wrap between the patient's skin and the accessory for cleanliness.

REFERENCE DEVICE COMPARISON		
ATTRIBUTE	**REFERENCE DEVICE** **Eclipse Treatment Planning System** **K172163**	**DEVICE** **3D Bolus Software (v1.2.2)**
PHOTON BEAM PLANNING	Yes	Yes, for photon beam bolus
ELECTRON BEAM PLANNING	Yes	Yes, for electron beam bolus
COMPENSATOR PLANNING	Yes	Yes, for 3D bolus printing
PLAN FOR HIGH DOSE RATE AFTERLOADER	Yes	Yes, for brachytherapy molds with source trajectory tubes
MANUAL LOW DOSE RATE BRACHYTHERAPY: SEEDS, LINE SOURCES, WIRE	Yes	Yes, for brachytherapy molds with source trajectory tubes
DICOM RT COMMUNICATION	Yes	Yes

Non-clinical Testing
Verification and Validation were performed for all features. System requirements can be traced to the test outcomes.

Conclusion of Non-Clinical testing
The outcome was that the product conformed to requirements, the defined user needs and intended uses and that there were no remaining software anomalies which affect safety or effectiveness.

Argument for Substantial Equivalence to the Predicate Device
A subset of features of the subject device are different from the predicate. These differences do not adversely impact performance of the device for its intended use nor do the differences raise new safety concerns. The nonclinical testing performed includes essential performance testing, functional performance characteristics testing and software verification and validation testing. All tests confirmed that the 3D Bolus System performs as intended and is substantially equivalent to the predicate.