Adaptiiv Medical Technologies Inc.
℅ Anastasiia Mereshchuk
Regulatory Affairs Manager
1344 Summer Street, Suite 406
Halifax, NS B3H 0A8
Canada

January 19, 2022

Re: K213438
Trade/Device Name: 3D Bolus Software Application, 3D Brachy Software Application, Patient-Matched 3D Printed Radiation Therapy Accessory
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: October 19, 2021
Received: October 22, 2021

Dear Anastasiia Mereshchuk:

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K213438

Device Name

3D Bolus Software Application;
3D Brachy Software Application;
Patient-Matched 3D Printed Radiation Therapy Accessory

Indications for Use *(Describe)*

3D Bolus and 3D Brachy applications are indicated for and intended for use as an accessory to a radiation therapy treatment planning system (TPS) to design patient-matched 3D printable accessories intended for use during external beam (photon or electron) radiation therapy, and surface brachytherapy. Users may choose to send the Stereolithography (STL) files to Adaptiiv Medical Technologies Inc. to 3D print the external beam radiation therapy accessories to the specification of the prescribing radiation therapy professional or 3D print either external beam or surface brachytherapy accessories in-house. If 3D printing is performed by Adaptiiv Medical Technologies Inc., 3D printed accessories will be sent to the requesting care center for the final quality control and acceptance by the trained radiation therapy personnel. The use of 3D Bolus and 3D Brachy applications as well as the 3D printed radiation therapy accessories is by prescription only.

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.

ADAPTIIV 1344 Summer Street, Suite 405 | Halifax, Nova Scotia | Canada | B3H 0A8

Manufacturer	Adaptiiv Medical Technologies Inc. (Adaptiiv) 1344 Summer Street, Suite 406 Halifax, NS, B3H 0A8 Canada
Primary Contact	Anastasiia Mereshchuk Regulatory Affairs Manager 1344 Summer Street, Suite 406 Halifax, NS, B3H 0A8 Canada
Date Summary Prepared	January 19, 2022
Trade Name	1. 3D Bolus Software Application 2. 3D Brachy Software Application 3. Patient-Matched 3D Printed Radiation Therapy Accessory
Product Code	MUJ
Device	System, Planning, Radiation Therapy Treatment
Regulation Description	Medical charged-particle radiation therapy system
Regulation number	892.5050
Device Class	Class II
Predicate Device	3D Bolus Software, Adaptiiv Medical Technologies Inc., K180289
Establishment registration:	3014873236

Device Description

Adaptiiv Medical Technologies Inc. solution is software as a medical device that consist of two (2) separate desktop applications:

a. 3D Bolus Software Application, which includes the Simple Bolus and Modulated Electron Bolus modules;
b. 3D Brachy Software Application, which includes the Surface Brachytherapy module.

The 3D Bolus and 3D Brachy software applications enable trained radiation therapy personnel to use DICOM and DICOM RT files from the radiation therapy treatment planning system (TPS) as inputs to produce Stereolithography (STL) files. Output STL files are compatible with the third-party 3D printers and allow the printing of the customized, patient-matched accessories for external beam radiation therapy, and/or surface brachytherapy applicators in-house or through Adaptiiv's OnDemand function. Accessories generated by the Adaptiiv's software must be verified by the trained radiation therapy professionals on their TPS for correctness prior to print initiation or accessory order through Adaptiiv OnDemand.

Adaptiiv's 3D printed patient-matched radiation therapy accessory is customizable accessory that expands the application of external-beam radiation therapy, allowing to overcome the skin-sparing effects inherent to high energy photons and electrons. If 3D printing is to be performed by Adaptiiv Medical Technologies Inc., desired external beam radiation therapy accessories will be

3D printed using the HP Jet Fusion 5200 Series 3D Printing Solution. Adaptiiv Medical Technologies Inc. has validated the Ultrasint® Thermoplastic polyurethane (TPU01) powder for use in 3D printing of radiation therapy accessories.

Indications for Use

3D Bolus and 3D Brachy applications are indicated for and intended for use as an accessory to a radiation therapy treatment planning system (TPS) to design patient-matched 3D printable accessories intended for use during external beam (photon or electron) radiation therapy, and surface brachytherapy. Users may choose to send the Stereolithography (STL) files to Adaptiiv Medical Technologies Inc. to 3D print the external beam radiation therapy accessories to the specification of the prescribing radiation therapy professional or 3D print either external beam or surface brachytherapy accessories in-house. If 3D printing is performed by Adaptiiv Medical Technologies Inc., 3D printed accessories will be sent to the requesting care center for the final quality control and acceptance by the trained radiation therapy personnel. The use of 3D Bolus and 3D Brachy applications as well as the 3D printed radiation therapy accessories is by prescription only.

Summary of technological characteristics

ATTRIBUTE	PREDICATE DEVICE 3D Bolus Software	DEVICE 3D Bolus and 3D Brachy Software Applications
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.	3D Bolus and 3D Brachy applications are indicated for and intended for use as an accessory to a radiation therapy treatment planning system (TPS) to design patient-matched 3D printable accessories intended for use during external beam (photon or electron) radiation therapy, and surface brachytherapy. Users may choose to send the Stereolithography (STL) files to Adaptiiv Medical Technologies Inc. to 3D print the external beam radiation therapy accessories to the specification of the prescribing radiation therapy professional or 3D print either external beam or surface brachytherapy accessories in-house. If 3D printing is performed by Adaptiiv Medical Technologies Inc., 3D printed accessories will be sent to the requesting care center for the final quality control and acceptance by the trained radiation therapy personnel. The use of 3D Bolus and 3D Brachy applications as well as the 3D printed radiation therapy accessories is by prescription only.
Target Population	Any patient prescribed radiation therapy requiring an applicable accessory device.	Any patient who is prescribed radiation therapy and requires an accessory device.
Anatomical Site(s)	Various	Various
Use Environment	Radiation oncology clinical setting	Radiation oncology clinical setting
Product Material	1. Polylactic Acid (PLA) filament 2. Thermoplastic Polyurethane (TPU) filaments	Accessories designed using 3D Bolus application are printed using: a. Polylactic Acid (PLA) filament b. Thermoplastic Polyurethane (TPU) filament c. Ultrasint® Thermoplastic polyurethane (TPU01) powder

ATTRIBUTE	PREDICATE DEVICE 3D Bolus Software	DEVICE 3D Bolus and 3D Brachy Software Applications
		Accessories designed using 3D Brachy application are printed using: a. Polylactic Acid (PLA) filament
Printer Compatibility	The following printers have been validated to be compatible with the 3D Bolus Software: • Axiom 20 from Airwolf 3D	The following printers have been validated to be compatible with the 3D Bolus software application: 1. Axiom 20 from Airwolf 3D 2. HP Jet Fusion 5200 Series The following printers have been validated to be compatible with the 3D Brachy software application: • Axiom 20 from Airwolf 3D
Bolus Product	3D printed variable thickness bolus.	3D printed variable thickness bolus.
Brachytherapy Product	3D printed surface brachytherapy applicator with source trajectory tunnels.	3D printed surface brachytherapy applicator with source trajectory tunnels.
Patient Product Plan	From treatment planning system. 3D Bolus software modifies plan for 3D printing within the treatment facility.	From treatment planning system. 3D Bolus and 3D Brachy applications modify the plan for 3D printing either by Adaptiiv Medical Technologies Inc. or within the treatment facility.
Communication with Treatment Planning System	DICOM and DICOM RT	DICOM and DICOM RT
Quality Assurance	Product designed by 3D Bolus Software is checked for accuracy on the treatment planning system before printing by in-house 3D printer or external 3D printing manufacturer utilizing verified and validated printing settings	1. 3D structures, designed in 3D Bolus and 3D Brachy applications, are verified for accuracy in the TPS before printing by the in-house 3D printer or external 3D printing manufacturer utilizing verified and validated printing settings. 2. If 3D printing is performed by Adaptiiv Medical Technologies Inc., dimensional fidelity and material uniformity will be evaluated as a condition for final product release to ensure product specifications are within the established acceptance criteria. Final product acceptance is performed by the trained radiation therapy professional at the care center.
Biocompatibility	It is recommended to place food-safe plastic wrap between the patient's skin and the accessory for cleanliness.	It is recommended to place food-safe plastic wrap between the patient's skin and the accessory for cleanliness.

Non-clinical Testing

Verification and Validation studies were performed to show substantial equivalence to the predicate device. The following evaluations were carried out to ensure that 3D Bolus and 3D Brachy software applications meet the established product specifications and can be used safely and effectively.

a. Unit Testing – to assess the 3D Bolus and 3D Brachy applications against the Functional Specifications. These tests are automated and are intended to verify the system at the code-level. Such testing ensures that at the functional level of the system, each software function performs as expected.
b. Integration Testing – to assess the 3D Bolus and 3D Brachy applications against the User Experience. The tests are designed to assess the functional units of the software end-to-end against the respective functional requirements.
c. System Testing – to assess user requirements at the system's external interfaces. Such testing addresses functional requirements of the software as they relate to the intended use. System testing evaluates software functionality at the intended operating environment.

Furthermore, the performance and compatibility of the printer and material set used to 3D print patient-matched radiation therapy accessories was assessed to demonstrate safety and efficacy of the 3D printed accessories. Spatial fidelity, dimensional consistency, and 3D printed material uniformity were assessed to ensure compliance with the required product specifications.

Argument for Substantial Equivalence to the Predicate Device

A subset of features of the subject device are different from the predicate device. These differences do not adversely impact performance of the device for its intended use. The nonclinical testing performed includes essential performance testing, functional performance characteristics testing, as well as software and radiation therapy accessory validation testing. All tests confirmed that 3D Bolus software application, 3D Brachy software application, and patient-matched 3D printed radiation therapy accessories perform as intended, can be used safely and effectively, and are substantially equivalent to the predicate device.