February 19, 2026

Adaptiiv Medical Technologies, Inc.
Olga Zhuk
Quality and Regulatory Manager
1559 Barrington St., Suite 200-D
Halifax, NS B3J 1Z8
Canada

Re: K260308
Trade/Device Name: TrueFit Bolus
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: January 30, 2026
Received: January 30, 2026

Dear Olga Zhuk:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, Ph.D.
Assistant Director
Radiation Therapy Team
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260308

Please provide the device trade name(s).

TrueFit Bolus

Please provide your Indications for Use below.

TrueFit Bolus is indicated for and intended to be placed on the patient's skin as an accessory to attenuate and/or compensate external beam (photon or electron) radiation during prescribed radiation therapy for the treatment of cancer or other non-malignant tissue conditions for which radiation therapy is indicated.
The device is for a single patient's use only and can be reused throughout the entirety of the treatment course.
The device is designed by the radiation therapy professional using patient imaging data as input and must be verified and approved by the trained radiation therapy professional prior to use.
The device is restricted to sale by or on the order of a physician and is by prescription only.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Special 510(k) Summary

K260308

Contact Details

Applicant Name	Adaptiiv Medical Technologies, Inc.
Applicant Address	1559 Barrington Street, Suite 200-D Halifax NS B3J 1Z8 Canada
Applicant Contact Telephone	902-442-9091
Applicant Contact	Olga Zhuk
Applicant Contact Email	olga.zhuk@adaptiiv.com

Device Name

Device Trade Name	TrueFit Bolus
Common Name	Medical charged-particle radiation therapy system
Classification Name	System, Planning, Radiation Therapy Treatment
Regulation Number	892.5050
Product Code	MUJ

Legally Marketed Predicate Devices

Predicate #	K243057
Predicate Trade Name	TrueFit Bolus
Product Code	MUJ

Device Description Summary

TrueFit Bolus is a 3D printed patient-matched radiation therapy accessory that expands the application of external beam radiation therapy by providing a patient-specific fit.

Patient imaging data from the treatment planning system (TPS) are used as inputs to generate digital design of the radiation therapy bolus (TrueFit) by 3D Bolus Software Application (K213438), previously developed by Adaptiiv. The resulting output Stereolithography (STL) file is compatible with the third-party 3D printers. A TrueFit Bolus can be 3D-printed using MJF with polyamide or polyurethane, or SLA with methacrylate photopolymer resin, based on the user's preference.

The bolus is used in radiation therapy when a patient requires the total prescription dose to be delivered on or near the skin surface. The bolus acts as a tissue-equivalent material placed on the patient skin to account for the build-up region of the treatment beam.

Intended Use/Indications for Use

TrueFit Bolus is indicated for and intended to be placed on the patient’s skin as an accessory to attenuate and/or compensate external beam (photon or electron) radiation during prescribed radiation therapy for the treatment of cancer or other non-malignant tissue conditions for which radiation therapy is indicated.

The device is for a single patient’s use only and can be reused throughout the entirety of the treatment course.

The device is designed by the radiation therapy professional using patient imaging data as input and must be verified and approved by the trained radiation therapy professional prior to use.

The device is restricted to sale by or on the order of a physician and is by prescription only.

Indications for Use Comparison

The updated Indications for Use for the TrueFit Bolus clarify and more explicitly describe the tissue conditions, without changing the fundamental intended use of the device. The device continues to be placed on the patient's skin as an accessory to attenuate and/or compensate external beam (photon or electron) radiation during prescribed radiation therapy. The added language, including "other non-malignant tissue conditions for which radiation therapy is indicated," clarifies the scope of tissue conditions treated within the established context of radiation therapy and reflects current clinical practice. This clarification does not introduce a new disease, condition, or distinguishable patient population. The intended patient population remains patients who are prescribed radiation therapy and require an accessory device to achieve the prescribed radiation dose distribution. The updated Indications for Use do not alter the device's mechanism of action, clinical application, or conditions of use. No new risks are introduced, and the safety and effectiveness of the TrueFit Bolus remain unchanged. Therefore, the updated Indications for Use do not constitute a new intended use.

Technological Comparison

The matter of the design change is addition of new material (methacrylate resin) using the SLA printing technology. The addition of rigid clear resin as a material for TrueFit Bolus expands the potential clinical use of the device due to the material transparency. It increases usability of the device during the fit of the device on the patient's anatomy.

Non-Clinical Tests Summary & Conclusions

Verification and Validation activities have been conducted using worst-case geometrical test samples and real-patient final devices.

The scope of the testing included evaluation of spatial fidelity and relevant radiological and physical properties directly affecting the performance and safety of the device. A summary of the testing is provided in Table 1.

Table 1. Summary of Non-Clinical Testing

Test	Objective	Acceptance Criteria	Results
Look & Feel	Evaluate surface quality, visual conformity to design, and usability.	High-quality surface finish; no visible defects; printed device visually matches STL; label and anatomical markers readable.	All samples met acceptance criteria and were rated high quality.
Spatial Fidelity	Confirm dimensional accuracy of printed device compared to STL design.	≥95% of measured points within ±3 mm of STL.	All samples had ≥95% of measured points within ±3 mm.
Physical Density	Confirm material density consistent with tissue-equivalent properties.	Mean density between 0.90–1.30 g/cc; SD ≤ ±0.10 g/cc.	Mean density 1.20 g/cc; SD 0.01 g/cc; all criteria met.
Radiological Density & Uniformity	Confirm radiological properties suitable for radiation therapy use.	Mean HU between –100 and 500; uniformity within ±100 HU.	HU range 52–111; uniformity within tolerance; all criteria met.

The results of the testing approaches demonstrated:

- Acceptable spatial fidelity, ensuring a precise fit of the device on the patient's anatomy and accurate delivery of radiation to the target treatment tissue.
- Physical density consistent with tissue-equivalent material.
- Radiological properties appropriate for treatment planning and dose delivery.

Verification and validation results support that the TrueFit Bolus is safe and effective for use in clinical conditions and remains substantially equivalent to the predicate device.