



Adaptiiv Medical Technologies, Inc.
Olga Zhuk
Quality and Regulatory Associate
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Canada

October 23, 2024

Re: K243057

Trade/Device Name: TrueFit Bolus; TrueFlex Bolus
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: September 27, 2024
Received: September 27, 2024

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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,

JULIE SULLIVAN -S

Julie Sullivan, Ph.D.

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

Indications for Use

510(k) Number (if known)

K243057

Device Name

TrueFit Bolus

TrueFlex Bolus

Indications for Use (Describe)

TrueFit/TrueFlex Bolus is indicated for and intended to be placed on the patient's skin as an accessory to attenuate and/or compensate the external beam (photon or electron) radiation during the treatment of various types of cancer.

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.

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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Special 510(k) Summary - K243057

Date of preparation 23rd of September 2024

Contact Details

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Device Name

Device Trade Name TrueFit Bolus, TrueFlex 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 # K213438
Predicate Trade Name Patient-Matched 3D Printed Radiation Therapy Accessory
Product Code MUJ

Device Description Summary

TrueFit/TrueFlex 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) or mould (TrueFlex) 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 is 3D printed by MJF technology using polyamide or polyurethane material. A Final TrueFlex Bolus device is manufactured by filling a mould with silicone.

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/TrueFlex Bolus is indicated for and intended to be placed on the patient's skin as an accessory to attenuate and/or compensate the external beam (photon or electron) radiation during the treatment of various types of cancer.

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 referenced submission (K213438) includes both software and hardware components: stand-alone desktop applications, 3D Bolus and 3D Brachy, and corresponding patient-matched 3D printed radiation therapy accessories. The scope of current submission is limited to the patient-matched boluses under a new Indications for Use statement. The Indications for Use statement has been updated to increase the clarity. It is merely a documentation update, no actual change in the substance or meaning in the intended uses of predicate and candidate devices has been implemented.

Technological Comparison

Patient-matched 3D printed radiation therapy accessories are divided into two devices under specific brand names depending on the qualities of material.

TrueFit Bolus: The matter of the design change is addition of new material (polyamide) using the same printing technology referred as applicable for predicate device (K213438) that can be used for manufacturing of TrueFit Bolus. The addition of polyamide as a material expands the potential clinical use of the device due to:

- Compared to TPU01 (MJF): Higher rigidity of the material. It increases safety and effectiveness of the device in clinical cases when immobilization is beneficial.
- Compared to PLA (FDM): Similar level of rigidity, but higher consistency of printing technology in terms of radiological properties. It increases safety and effectiveness of the device in clinical use ensuring uniformity of radiological density and as a result - accurate delivery of radiation during the treatment.

TrueFlex Bolus: The design change involves the addition of a new manufacturing method for the device, using the following materials:

- Silicone - manufacturing of TrueFlex Bolus.
- Polylactide (FDM), polyamide (MJF), photopolymer resin (SLA) – production of manufacturing accessories (moulds).

The addition of silicone as a material expands the potential use of the device due to its higher flexibility. It increases safety and effectiveness of the device compared to the predicate device (K213438) due to the following reasons:

- Silicone bolus conforms to convex and concave surfaces as well as fill shallow cavities, reducing air gaps and ultimately delivering a more accurate treatment.
- Due to the flexibility of the material, it facilitates comfortable placement on the patient.

As a part of the design changes, nonclinical assessments were performed to ensure the technologies and materials compatibility with device design in facilitating the manufacturing of radiation therapy accessories. All tests verified that the chosen methods performed as intended and did not affect the overall safety and effectiveness of the device and are equivalent compared to the ones covered by referenced submission.

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.

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.
- Acceptable physical and radiological properties of the device, enabling its use during radiation therapy treatment according to the treatment plan.

Verification and Validation testing results are considered as evidence of overall safety and effectiveness of the device, as compared to the predicate, for use in clinical conditions.

Performance testing results demonstrate substantial equivalence to the predicate device (K213438) and are considered as evidence of the overall safety and effectiveness of the device, as compared to the predicate, for use in clinical conditions.