



Adaptiiv Medical Technologies, Inc.
Olga Zhuk
Quality and Regulatory Associate
1969 Upper Water Street, Suite 906
Halifax, NS B3J 3R7
Canada

August 30, 2024

Re: K241318

Trade/Device Name: Nova Surface Applicator (ADPT-ONDEM-3DPRT-BRA)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: May 10, 2024
Received: May 10, 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.

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.
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DHT8C: Division of Radiological
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OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K241318

Device Name

Nova Surface Applicator (ADPT-ONDEM-3DPRT-BRA)

Indications for Use (Describe)

Nova Surface Applicator is indicated for and intended to be placed on the patient's skin to navigate an HDR radiation source during the treatment of various types of cancer using brachytherapy.

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

The device is designed by radiation therapy professionals 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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510(k) Summary - K241318

Contact Details

<i>Applicant Name</i>	Adaptiiv Medical Technologies, Inc.
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<i>Applicant Contact</i>	Olga Zhuk
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Device Name

<i>Device Trade Name</i>	Nova Surface Applicator (ADPT-ONDEM-3DPRT-BRA)
<i>Common Name</i>	Medical charged-particle radiation therapy system
<i>Classification Name</i>	System, Planning, Radiation Therapy Treatment
<i>Regulation Number</i>	892.5050
<i>Product Code</i>	MUJ

Legally Marketed Predicate Devices

<i>Predicate #</i>	K213438
<i>Predicate Trade Name</i>	Patient-Matched 3D Printed Radiation Therapy Accessory
<i>Product Code</i>	MUJ

Device Description Summary

Adaptiiv's Nova Surface applicator is a 3D printed patient-matched radiation therapy accessory that expands the application of brachytherapy by providing a patient-specific fit and catheter trajectory design.

Patient imaging data from the treatment planning system (TPS) are used as inputs to generate digital design of the surface brachytherapy applicator by 3D Brachy Software Application (K213438), previously developed by Adaptiiv. The resulting output Stereolithography (STL) file is compatible with the third-party 3D printers.

Nova Surface applicator navigates a radiation source toward tumors located closely to or on the surface of the body (e.g. skin cancers). It fits the patient's anatomy by means of a patient-specific contact surface ensuring that optimal dose is delivered to a target surface of the body. It accommodates catheter tunnels which guide the HDR brachytherapy radiation source according to the patient-specific design input chosen by users.

A surface brachytherapy applicator device is 3D printed by Stereolithography (SLA) technology using methacrylic resin.

Intended Use/Indications for Use

Nova Surface Applicator is indicated for and intended to be placed on the patient's skin to navigate an HDR radiation source during the treatment of various types of cancer using brachytherapy.

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

The device is designed by radiation therapy professionals 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 brachytherapy accessory 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

Nova Surface Applicator is manufactured using SLA technology with clear resin. Usage of SLA technology as well as clear resin for manufacturing of brachytherapy applicators increases the safety and effectiveness of the device compared to FDM technology and PLA material used for predicate device (K213438) manufacturing due to the following reasons:

- High accuracy and tolerance of printing ensure proper fit of the device with the patient anatomy as well as accurate delivery of radiation during the treatment.
- Smoother surface finish improves overall comfort while using patient-specific devices intended to be placed on the skin surface.
- The brachytherapy applicator is used as a navigator of radiation by integrating catheter tunnels in its design. The catheter that will guide a wire with radioactive material is inserted inside the applicator's tunnels prior to the brachytherapy treatment session. The transparency of the final device printed with clear resin increases its usability and level of control during the catheter placement as well as fit of the device on the patient's anatomy.

As a part of the design change, a nonclinical assessment was performed to ensure SLA technology and material compatibility with device design in facilitating the 3D printing of brachytherapy accessories. All tests verified that the chosen manufacturing technology performed as intended and did not affect the overall safety and effectiveness of the device and are beneficial compared to the previously used technology.

Non-Clinical Tests Summary & Conclusions

Performance Testing conducted for the Nova Surface Applicator includes two testing approaches:

1. Post-production verification: a set of testing aimed to demonstrate that the device's functional features and properties directly affecting the device's performance, conform to the requirements defined in correspondence with the intended use. The batch of the tests has been performed on worst-case samples as well as on the final device - real patient datasets - and included the following:

- Look, feel, surface quality.
- Inner structure consistency (mass consistency and dimensional fidelity).
- The functionality of catheter tunnels (tunnel accessibility, orientation, inter-tunnel, and source-to-surface distances).
- Labels legibility.
- Additional features functionality (dosimetry pockets and alignment guides).

2. Simulated performance testing: Evaluation of the spatial fidelity and fit of the patient-specific devices by virtually positioning a CT scan of the device with respect to a DICOM-RT structure that represents a faithful reproduction of a patient's anatomy at the time of scanning. This test is intended to ensure that a key functional feature - patient-specific contact surface, directly affecting intended device performance - conforms to user needs and performance requirements and provides enough accuracy to fit the patient's anatomy.

The results of both testing approaches demonstrated:

- High printing accuracy of the key functional features and robustness of functional key property (density of the material after printing) in conformance with performance requirements.
- High accuracy in terms of spatial fidelity providing a precise fit of the device on the patient's anatomy and delivery of the radiation to the treatment target tissues.
- The technological and validation methods used in the testing provide reliable results and are considered applicable to ensure product quality during the production process.

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.