RadTec Medical Devices, Inc.
% Michelle Rubin-Onur, Ph.D.
Regulatory Specialist
AcKnowledge Regulatory Strategies LLC.
2251 San Diego Ave, Suite B-257
SAN DIEGO CA 92110

July 6, 2020

Re: K200652
Trade/Device Name: Lollipop BiteBlock
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: June 11, 2020
Received: June 12, 2020

Dear Dr. Rubin-Onur:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K200652

Device Name
Lollipop BiteBlock

Indications for Use *(Describe)*

The Lollipop BiteBlock from RadTec Medical Devices, Inc. is intended to be used for repeat positioning and immobilization of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

It is intended to be used by or under the direction of a licensed physician.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

DATE PREPARED
May 5, 2020

MANUFACTURER AND 510(k) OWNER
RadTec Medical Devices, Inc.
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DEVICE INFORMATION

Proprietary Name/Trade Name:	Lollipop BiteBlock
Common Name:	Accelerator, Linear, Medical
Regulation Number:	21 CFR 892.5050
Class:	Class II
Product Code:	IYE
Premarket Review:	OPEQ/Division of Radiological Health (DRH) Division of Radiological Health (DRH)

PREDICATE DEVICE IDENTIFICATION
The Lollipop BiteBlock is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Regulation Number*	*Product Code*	*Primary Predicate*
K153270	TruGuard Custom Tongue and Jaw Positioner / Bionix Development Corporation	21 CFR 892.5050	IYE	✓

The predicate device has not been subject to a design related recall.

510(k) Summary

DEVICE DESCRIPTION

The Lollipop BiteBlock is a multi-configuration, single patient reusable device intended to be used for the planning, positioning, and re-positioning of a patient's oral cavity while they undergo or receive a course of external beam radiation therapy for the treatment of cancer and other diseases. The Lollipop BiteBlock is designed for use in radiation therapy departments in hospitals and/or free-standing treatment centers.

The Lollipop BiteBlock is available in four configurations: lateral tongue localization (LTL), mouth open tongue forward (MOTF), mouth open tongue depressed (MOTD), and mouth open tongue (forward) closed (MOTC). The choice of which configuration is appropriate to the patient is left to the physician's discretion.

The Lollipop BiteBlock is manufactured using 3D printing technology. At least one sample, per lot, from each of the four configurations is measured to ensure that it meets device specifications. The Lollipop BiteBlock is provided to the physician as the final finished device. The 3D electronic files are not sent to the physician at any time.

INDICATIONS FOR USE

The Lollipop BiteBlock from RadTec Medical Devices, Inc. is intended to be used for repeat positioning and immobilization of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

It is intended to be used by or under the direction of a licensed physician.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

RadTec Medical Devices, Inc. believes that the Lollipop BiteBlock is substantially equivalent to the predicate device based on the information summarized here:

The subject device has a similar design and dimensions and uses similar or identical materials as the device cleared in K153270. The subject device has the same intended use and similar technological characteristics to the device cleared in K153270. The Lollipop BiteBlock has undergone testing to ensure that any differences in technological characteristics do not affect safety and effectiveness when compared to the predicate device.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Lollipop BiteBlock.

Patient contacting material was subjected to biocompatibility testing in compliance with ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing with a risk management process*.

510(k) Summary

The following tests were performed to demonstrate equivalence to the predicate device

- Vertical Tongue Force: A force of ≥ 175 lbF was applied to represent the worst-case scenario as it is 10-20% over the max force of the human tongue. Each construct was visually inspected for any internal or external fractures or cracks. None of the devices had any breaking, cracking, or fracturing therefore meeting the acceptance criteria and passing the test.

- "Bite" Crush Force: The subject device was placed between the upper and lower jaws of an anthropomorphic jaw model with teeth to simulate a realistic treatment position and distribution of force. A force of ≥ 250 lbF was applied to represent worst-case scenario as it is 10-20% over the max force of the human jaw. Each construct was visually inspected for any internal or external fractures or cracks. None of the devices had any breaking, cracking, or fracturing therefore meeting the acceptance criteria and passing the test.

- Backscatter Radiation Attenuation: The subject device was placed into a solid water phantom with sheets of GafChromic EBT3 film placed above and below the device. A dose of 4 Gy was used for irradiation. Irradiation was performed twice, once with a lead sheet (to generate back scatter) and once without. The lead sheet was used as a worst-case condition as it has a significantly higher backscatter than teeth, dental fillings, or other dental appliances. The test found that the subject device has a shielding efficacy just below "1" (0.962) demonstrating shielding performance similar to that of the predicate.

CONCLUSION

Based on the testing performed it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed Lollipop BiteBlock are assessed to be substantially equivalent to the predicate device.