Papricalab
% Jonghyum Kim, CEO
GMS Consulting
B612, 66, Cheongcho-ro, Deogyang-gu
Goyang-si, Gyeonggi-do 10543
SOUTH KOREA

November 15, 2023

Re: K231852
Trade/Device Name: BinkieRT
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: October 10, 2023
Received: October 17, 2023

Dear Jonghyum Kim:

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 -S

Digitally signed by Lora D. Weidner -S
Date: 2023.11.15 14:05:58 -05'00'

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

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.

510(k) Number *(if known)*
K231852

Device Name
BinkieRT

Indications for Use *(Describe)*
The BinkieRT is intended to be used for repeat positioning and immobilization of a patient's tongue and jaw while undergoing or receiving a course of external beam radiation therapy for treatment of cancer and other diseases. It is intended to be used by or under the direction of a licensed physician. BinkieRT is meant for use with 6 MV photon beams 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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K231852

510(k) Summary

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

June 20, 2023

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: Papricalab
- Address: 11, Yulgok-ro 14-gil, Jongno-gu, Seoul, Republic of Korea
- Contact Name: Sohyeon Woo
- Telephone No.: +82-2-742-6161
- Fax No.: +82-2-742-6162
- Email Address: sohyeon6125@papricalab.com

3. Trade Name, Regulation Name, Classification [21 CFR 807.92(a)(2)]

Trade/Device Name	BinkieRT
Common Name	Oral fixation device
Regulation Number	21 CFR 892.5050
Regulation Name	Medical charged-particle radiation therapy system
Regulation Class	Class II
Product Code	IYE

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

Predicate device

- 510(k) Number: K183374
- Applicant: POLL Medical LLC
- Trade/Device Name: GrayDuck Stent
- Regulation Number: 21 CFR 892.5050
- Regulation Name: Medical charged-particle radiation therapy system
- Regulation Class: Class II
- Product Code: IYE

Predicate device has not been subject to a design-related recall

Reference device

- 510(k) Number: K153270
- Applicant: POLL MedicBionix Development Corporation
- Trade/Device Name: TruGuard Custom Tongue and Jaw Positioneral LLC
- Regulation Number: 21 CFR 892.5050
- Regulation Name: Medical charged-particle radiation therapy system
- Regulation Class: Class II
- Product Code: IYE

Predicate device has not been subject to a design-related recall

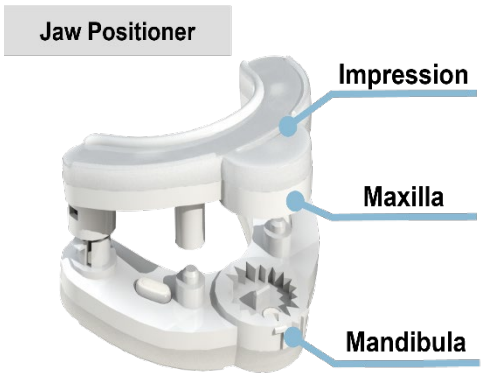
5. Description of the Device [21 CFR 807.92(a)(4)]

5.1 Device Principle

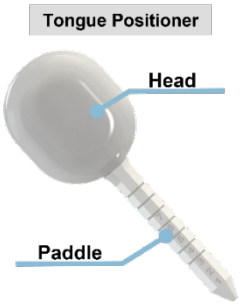
It is a patient-specific medical device that is mounted in the oral cavity of the patient to fix the temporomandibular joint in the treatment of head and neck radiation, and the planned dose is accurately delivered to the target area, and the tongue is moved in one direction to be spaced apart to minimize the exposure of normal tissue to the surrounding area.

5.2 Device configuration and description

<Jaw Positioner>

Part name	Description	Picture
Impression	Patient-specific impression collection	
Maxiila	Maxillary support and fixation	
Mandibula	Mandibular support and fixation	

<Tongue Positioner>

Part name	Description	Picture
Head	Tongue pressure fixation	
Paddle	Adjusting the insertion depth of the pressing body	

<Column>

Part name	Description	Picture

Rotation Guide	Supports the central axis of the fixed body and the grip force of the upper and lower jaw, penetrates the pressing body, and serves as a guide for adjusting the depth axis rotation	

5.3 How to use the device

1) Insert the Column into the pressure paddle to adjust the insertion depth in the cavity.
2) The axis is determined by fitting the rotating Column to the tooth portion of the fixture.
3) Combine the maxilla and mandibula with the pillars.
4) The tongue is fixed by adjusting the rotation and depth according to the patient's treatment area.

6. Indications for use [21 CFR 807.92(a)(5)]

The BinkieRT is intended to be used for repeat positioning and immobilization of a patient's tongue and jaw while undergoing or receiving a course of external beam radiation therapy for treatment of cancer and other diseases. It is intended to be used by or under the direction of a licensed physician.

BinkieRT is meant for use with 6 MV photon beams only.

7. Determination of Substantial Equivalence

7.1 Technological Characteristics

Summary of technological characteristics of the device compared to the predicate device. [21 CFR 807.92(a)(6)]

The BinkieRT is substantially equivalent to legally marketed predicate device(GrayDuck Stent) with respect to indications for use and technology characteristics.

The table below presents comparisons for device:

[Table 1. Comparison of Proposed Device to Predicate Device]

	Proposed Device	Predicate Device	Reference device	SE Note
Manufacture	**Papricalab**	**POLL Medical LLC**	**Bionix Development Corporation**	**-**
Name	BinkieRT	GrayDuck Stent	TruGuard Custom Tongue and Jaw Positioner	-
510(k) No.	K231852	K183374	K153270	-
Product code	IYE	IYE	IYE	Same
Regulation Number	21 CFR 892.5050	21 CFR 892.5050	21 CFR 892.5050	Same
Classification	Class II	Class II	Class II	Same
Appearance				Equivalent.
Intended for use	The BinkieRT is intended to be used for repeat positioning and immobilization of a patient's tongue and jaw	The GrayDuck Stent™ custom tongue and jaw positioner from POLL Medical LLC is intended to be used for repeat	The TruGuard Custom Tongue and Jaw Positioner from Bionix Development Corporation is intended to	Equivalent. No new issues on safety and effectiveness

	while undergoing or receiving a course of external beam radiation therapy for treatment of cancer and other diseases. It is intended to be used by or under the direction of a licensed physician. BinkieRT is meant for use with 6 MV photon beams only.	positioning and immobilization of a patient's tongue and jaw while undergoing or receiving a course of external beam radiation therapy for treatment of cancer and other diseases. The GrayDuck Stent is intended to be used by or under the direction of a licensed physician.	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.	
Clinical Application	Radiation Therapy Treatment	Radiation Therapy Treatment	Radiation Therapy Treatment	Same
Clinical Setting/ Site of Use	Prescription device for clinic/ Hospital use	Prescription device for clinic/ Hospital use	Prescription device for clinic/ Hospital use	Same
User	Licensed physician	Licensed Physician	Licensed Physician	Same
Material	Jaw Positioner, Tongue Positioner : Molded Plastic Impression Layer, Head of Tongue Positioner :Moldable EVA (ethylene vinyl acetate) Thermoplastic	Arch Tray (Main Stent) & Tongue Deviation Components : Molded Plastic Dental Impression Insert : Moldable EVA (ethylene vinyl acetate) Thermoplastic	Arch Tray (Main Stent) & Tongue Deviation Components : Molded Plastic Dental Impression Insert : Moldable EVA (ethylene vinyl acetate) Thermoplastic	Same
Dual bite trays	Yes	Yes	Yes	Same
Allows for open Jaw positioning	Yes	Yes	Yes	Same
Positions the Tongue	Yes	Yes	Yes	Same
Shielding from backscatter radiation	Yes	Yes	Yes	Same
MRI Safe	Yes	Yes	Yes	Same

The table also provides rationale for a little difference in support of substantial equivalence to the Predicate devices

[Table 2. Little difference with Predicate Device]

Justification to Support Substantial Equivalence
There are no significant differences between BinkieRT and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to predicate devices in indications for use and technology characteristics.

Non-Clinical Test summary

The BinkieRT comply with voluntary standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment and usability. The following data were provided in support of the substantial equivalence determination:

1) Biocompatibility

Bio-compatibility test is performed according to below:

- FDA Guidance document Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process
- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices — Part 10: Tests for skin sensitization

2) Bench Testing

- X-ray backscatter shielding performance

Bench tests were conducted to verify the shielding capabilities of the Binkie RT against secondary low-energy backscatter radiation emitted by metal piling bridgework. Subjects were exposed to a 6 MV high energy photon beam and the backscatter radiation dose was radiation dose was assessed by measuring the exposure density of the industry standard Gafchromic EBT3 film placed adjacent to the subject. The Dose Enhancement Ratio was defined as the backscattered radiation dose produced by the subject divided by a "baseline" dose (backscattered radiation produced without the subject in the photon beam). Shielding effectiveness was indicated by the Dose Enhancement Ratio. Values greater values greater than 1 indicate an increased dose of backscatter radiation to the patient and a poor shielding effect, while a ratio of 1 indicates complete shielding with no dose of backscatter radiation delivered to the patient.

The Dose Enhancement Ratio of the assembled BinkieRT is just below 1.0, indicating near perfect shielding. Shows the nearly complete shielding effectiveness of the Binkie RT device in shielding backscattered radiation.

- EVA dental impression depth comparation test

Bench testing was performed to compare the depth of the EVA impression to verify that the depth of the dental arch impression was not significantly affected by bite time. using a force gauge (i.e., occlusal force gauge) and anthropomorphic jaws, a force of ~800N was applied to the EVA once before treatment and repeated after each 2.25 Gy fraction of a total 67.5 Gy dose to the BinkieRT (i.e., 30 fractions). The force was selected as the reported maximum human bite force using a soft bite surface. Impression depth was measured with calipers for every 10 fractions and analyzed over time to detect changes in the structural integrity of the BinkieRT over the course of treatment. An effect of bite time was evaluated by measuring the deviations of impression depth with fractions compared to the initial impression depth. After the 67.5 Gy was completed, the final impression depth was compared to the previous 35 fractions.

The measured impression depth must be within the standard deviation of the initial impression depth measurements. The impression depth comparison test showed that the depth was not significantly affected by the time frame, and the test performance was similar to that of the predicate. The BinkieRT produces similar impression depths when comparing its current timeframe to the longer timeframe indicated in the Predicate device's Instructions for Use.

The non-clinical performance test results provide evidence that the BinkieRT is safe and effective when used as intended.

3) Validation

- Packaging process validation

Through several tests conducted for validation of the packaging process, optimized packaging process parameters among various packaging process conditions were identified.

The nylon packaging, which was packaged through the vacuum packaging machine, was stably packaged under the conditions of 'vacuum step 100, adhesion step 10, cooling step 35', and the adhesive strength of the packaging also showed good results.

It has been verified through various tests that the wrapping paper of "BinkieRT" thermally bonded

through the validated packaging process can maintain a consistent and perfect state and has the ability to protect the produet from contaminants

- Cleaning process validation

The cleaning process validation was performed on the "Oral_001 (O-TYPE)", which is a worst case sample, using the cleaner that has completed installation and operation qualification (IQ / OQ).

'Asa verification method for verifying the effectiveness of the cleaning process, it met the test criteria in the physicochemical test (TOC, pH, Electrical conductivity test) performed after the final cleaning. Also, cleaning agent residue test (HPLC), residue evaporation, microorganism test (Bioburden test) and dry Validation test were suitable for the acceptable criteria,

Based on the validation results, we can conics that cleaning process is validated and itis effective to cleaning the 'BinkieRT"

Clinical Test Summary

Clinical testing was not required to demonstrate the substantial equivalence of the BinkieRT to its predicate devices.

8. Conclusion [21 CFR 807.92(b)(3)]

The BinkieRT have similar intended use and technical characteristics to the predicate device.

Based on that information, we conclude that the differences between the proposed device and predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness.