Kallisio, Inc
℅ Mary Lou Mooney
Consultant
2925 Richmond Ave., Suite 1200
HOUSTON, TX 77098

December 22, 2023

Re: K232293
Trade/Device Name: kallisio stentra™ oral stent
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: July 31, 2023
Received: August 1, 2023

Dear Mary Lou Mooney:

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.
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)*

K232293

Device Name
kallisio Stentra Oral Stent

Indications for Use *(Describe)*

The kallisio Stentra™ oral stent is intended to be used for repeat positioning and immobilization of a patient's tongue and jaw while undergoing a course of external beam radiation therapy for treatment of cancer and other diseases. The kallisio Stentra oral stent 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary (as required by 21CFR 807.92)

I. SUBMITTER

Kallisio, Inc
2925 Richmond Ave, Suite 1200
Houston, TX 77098
Phone: 650-464-5335

Contact Person:	Mary Lou Mooney (Consultant)
Date Prepared:	November 24, 2023

II. DEVICE

Name of Device:	Kallisio Stentra™ OralStent
Common or Usual Name:	Bite Block (positioner)
Classification Name:	Accessory to Accelerator, Linear, Medical
Regulatory Class:	892.5050
Product Code:	IYE

III. PREDICATE DEVICE

Predicate Device:	GrayDuck Stent™ (K183374)

IV. DEVICE DESCRIPTION

The Kallisio Stentra Oral Stent is a single patient, reusable custom tongue and jaw positioner used for repeat positioning and immobilization of a patient's tongue and jaw while receiving a course of external beam radiation therapy for treatment of cancer and other diseases. Q-bite bite block accessories are supplied separately.

The Stentra Stent is a prescription device.

V. INDICATIONS FOR USE

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

The Indication for Use for the Stentra Stent is identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate device are based on the following same technological elements:

- A custom-fitted polymeric stent positioned inside the mouth.
- Positioning of the device to open and immobilize the jaw and deviate the tongue away from the radiation area.

The following technological differences exist between the subject device and the predicate device:

- Use of a different polymeric material.
- Method of customization.

Subject and Predicate Device Comparison

Description	Kallisio Stentra (subject device)	GrayDuck Stent K183374 (predicate device)	Compared to Subject Device
Intended Use	Intended to provide repeat positioning and immobilization of a patient's tongue and jaw.	Intended to provide repeat positioning and immobilization of a patient's tongue and jaw.	Same
Indication for Use	Repeat positioning and immobilization of a patient's tongue and jaw while undergoing a course of external beam radiation therapy for treatment of cancer and other diseases.	Repeat positioning and immobilization of a patient's tongue and jaw while undergoing a course of external beam radiation therapy for treatment of cancer and other diseases.	Same
Target Population	Patients undergoing external beam radiation therapy for treatment of cancer and other diseases.	Patients undergoing external beam radiation therapy for treatment of cancer and other diseases.	Same
Principles of Operation	Device is inserted into the mouth to open and immobilize the jaw and deviate the	Device is inserted into the mouth to open and immobilize the jaw and deviate the	Same

Description	Kallisio Stentra (subject device)	GrayDuck Stent K183374 (predicate device)	Compared to Subject Device
	tongue away from the treatment area.	tongue away from the treatment area.	
Technology	Polymeric stent positioned inside the mouth	Polymeric stent positioned inside the mouth	Same
Clinical Setting/Site of Use	Prescription device for clinic/hospital use	Prescription device for clinic/hospital use	Same
Custom-fitted to Patient?	Yes	Yes	Same
Material	Polymeric material (nylon)	Polymeric material (Molded plastic, moldable EVA (ethylene vinyl acetate)	Similar
Patient Use	Single patient, multi-use	Single patient, multi-use	Same
Supplied Sterile/Non Sterile?	Supplied non-sterile	Supplied non-sterile	Same
Allows for jaw positioning?	Yes	Yes	Same
Positions the tongue?	Yes, allows the tongue to be positioned to the left, right, downward or upward.	Yes, allows tongue to be positioned to the left, right or downward.	Same, with the additional flexibility to position the tongue upward.
Attaches to a radiotherapy face mask?	Yes	Yes	Same
Shielding from backscatter radiation?	Yes	Yes	Non-clinical testing of subject device performed with 6MV photon beam. Predicate device non-clinical testing performed with 6MV and

Description	Kallisio Stentra (subject device)	GrayDuck Stent K183374 (predicate device)	Compared to Subject Device
			18 MV photon beam.

VII. PERFORMANCE DATA

Non-Clinical Testing

Biocompatibility testing was conducted in accordance with FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*. Biocompatibility testing included cytotoxicity, irritation and sensitization. Results demonstrated acceptable biocompatibility of the Stentra device for its intended contact category and duration.

Performance testing assessed corrosion-resistance and device mechanical strength. Test units were immersed in a simulated saliva solution at body temperature followed by immersion in boiling water. Gross and microscopic (20x) examination of the Stentra device showed no evidence of corrosion or surface changes. Device mechanical strength was demonstrated by applying a compressive load to the device that is 2x the maximum force that can be applied by a human jaw. Gross and microscopic (20x) examination of the Stentra device showed no cracks or fractures. Attenuation testing with a 6 MV photon beam demonstrated similar shielding performance to that of the predicate device.

VIII. CONCLUSIONS

The similarity of design, features, composition and function and the non-clinical test results demonstrate that the subject device is substantially equivalent to the predicate device for repeat positioning and immobilization of the jaw and tongue during external beam radiation for cancer and other diseases.