POLL Medical LLC
% Ms. Alyssa Thomas
Principal Consultant
Allegiance Regulatory Consulting LLC
16642 SW Lansford Ct.
BEAVERTON OR 97007

February 26, 2019

Re: K183374
Trade/Device Name: GrayDuck Stent™
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: February 6, 2019
Received: February 8, 2019

Dear Ms. Thomas:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183374

Device Name
GrayDuck Stent™

Indications for Use *(Describe)*

The GrayDuck Stent™ custom tongue and jaw positioner from POLL Medical LLC 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. The GrayDuck 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.

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5. 510(K) SUMMARY OR 510(K) STATEMENT

Please see the 510(k) Summary, as required by 21 CFR 807.92 (c), for the GrayDuck Stent device following this page.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA (Safe Medical Devices Act) 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K183374

5.1. Submitter Contact Information

Name:	POLL Medical
Address:	8630 SW Scholls Ferry Road, Suite 225 Beaverton, OR 97008, USA
Phone:	503-319-3096
Fax:	971-217-9004
Contact:	Adrian Polliack, PhD
Date Prepared:	November 27, 2018

5.2. Device Identification

Trade Name:	GrayDuck Stent™
Common Name:	Bite Block (positioner)
Classification Name:	Patient Support Accessory to Accelerator, Linear, Medical
Regulatory Class:	892.5050
Product Code:	IYE

5.3. Legally Marketed Predicate Device

K153270 Bionix Development Corporation's TruGuard Custom Tongue and Jaw Positioner

5.4. Device Description

The GrayDuck Stent™ custom tongue and jaw positioner from POLL Medical is design to provide reproducible opening of the jaw and positioning of the tongue for a patient undergoing external beam radiation therapy treatment. In addition, the GrayDuck Stent provides shielding against secondary low-energy backscatter radiation emitted from

metal fillings and bridgework. The stent is a custom-fitted bite block with a boil-and-bite insert that allows for formation of dental impressions for repeatable positioning. The Stent is made of an injection molded plastic material with moldable EVA bite inserts. The GrayDuck Stent is available in two sizes. The patient's tongue can be deviated laterally left, laterally right, downward (depressed), or a combination of laterally left/depressing or laterally right/depressing by using one of the GrayDuck Stent tongue paddles, which allows many degrees of freedom in positioning the patient's tongue and jaw.

5.5. Intended Use/Indications for Use

Intended Use: The GrayDuck Stent is intended to provide repeatable positioning and immobilization of a patient's tongue and jaw during external beam radiation therapy treatment.

Indication for Use: The GrayDuck Stent custom tongue and jaw positioner from POLL Medical LLC 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. The GrayDuck Stent is intended to be used by or under the direction of a licensed physician.

5.6. Summary of Technological Characteristics

The GrayDuck Stent is a custom-fitted bite block with a boil-and-bite insert that allows for the formation of dental impressions for repeatable positioning and immobilization of a patient's jaw and tongue. By using the patient's unique dental impressions of both upper and lower teeth (dental arches), the GrayDuck Stent is fit reproducibly for each successive radiation therapy treatment. The boil-and-bite insert material is used in both the subject device and the predicate (the TruGuard device). The GrayDuck Stent is available in multiple sizes and includes tongue paddles for positioning and immobilizing the patient's tongue. With the adjustable tongue paddles and variation in sizes, the GrayDuck sent allows the jaw to be held open at pre-set angles and the tongue to be deviated away from the treatment area. The TruGuard uses similar technology, a plastic indexing tab and tongue depressor to achieve the pre-set angle and tongue depression. The GrayDuck Stent provides additional range of tongue deviation through the selection of either a Right, Left or Depressing paddle. The additional flexibility create by the paddle options provides clinicians more choices to help ensure the patient's tongue is positioned away from the radiation treatment area. Similar to the TruGuard's indexing tab that allows the jaw to be held open at pre-set angles, the GrayDuck Stent size options

allow variation in the pre-set angle of the jaw. A table comparing the key features of the subject device and the predicate device is provided below (**Error! Reference source not found.**).

Table 5-1 Subject & Predicate Device Comparison

Device	**GrayDuck Stent** **(Subject Device)**	**TruGuard Custom Tongue & Jaw Positioner (K153270)**
Intended Use	The GrayDuck Stent is intended to provide repeatable positioning and immobilization of a patient's tongue and jaw during external beam radiation therapy treatment.	Repeat positioning and immobilization of patients receiving external beam radiation.
Indication for Use	The GrayDuck Stent™ custom tongue and jaw positioner from POLL Medical LLC 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. The GrayDuck Stent is intended to be used by or under the direction of a licensed physician.	The TruGuard Custom Tongue and Jaw Positioner from Bionix Development Corporation is intended to be used for repeat positioning and immobilization of patients 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.
Clinical Application	Radiation Therapy Treatment	Radiation Therapy Treatment
Clinical Setting/Site of Use	Prescription Device for Clinic / Hospital Use	Prescription Device for Clinic / Hospital Use
Technology Characteristics		
Material – Arch Trays (Main Stent) & Tongue Deviation Components	Molded Plastic	Molded Plastic
Material – Dental Impression Insert	Moldable EVA (ethylene vinyl acetate) Thermoplastic	Moldable EVA Thermoplastic
Dual Bite Trays	Yes	Yes
Allows for Open Jaw Positioning	Yes	Yes
Principles of Operation & Performance		
Procedure for Initial Patient Fitting	Yes	Yes
Reproducible Patient Positioning	Yes	Yes

Device	GrayDuck Stent (Subject Device)	TruGuard Custom Tongue & Jaw Positioner (K153270)
Positions the Tongue	Yes	Yes
Attaches to Face Mask	Yes	Yes
Shielding from Backscatter Radiation	Yes	Yes
MRI Safe	Yes	Yes

5.7. Performance Data

Non-Clinical Testing – The application includes detailed discussions of nonclinical testing. In all instances, the GrayDuck device preformed as intended. Biocompatibility testing was performed, demonstrating that the plastic polymer of the main stent body and the EVA thermoplastic insert are acceptable based on the contact category for the GrayDuck Stent. Attenuation testing was done to determine the GrayDuck Stent's backscatter shielding performance. The dose ratio for both high-energy photon beam levels tested (6 MeV and 18 MeV) were just below 1, demonstrating shielding performance similar to that of the predicate. An EVA dental impression depth comparison test was completed to verify that dental arch impression depth is not significantly affected by the bite timeframe. The GrayDuck Stent produces similar impression depth when comparing its current timeframe to the longer timeframe given in the predicate device's instructions for use. The nonclinical evaluates provide evidence of the GrayDuck Stent's safety and effectiveness when used as intended.

Clinical Testing - Clinical testing is not included in this submission

5.8. Substantial Equivalence

The GrayDuck Stent is as safe and effective as the predicate, the TruGuard Custom Tongue and Jaw Positioner. The GrayDuck Stent has the same intended uses and indications for use as the predicate device. The GrayDuck Stent has similar technological characteristics and principles of operation as its predicate device. The minor technological differences between the GrayDuck Stent and its predicate devices raise no new issues of safety or effectiveness. The Performance data demonstrates that the GrayDuck is as safe and effective as the TruGuard. Thus, the GrayDuck is substantially equivalent.

5.9. Conclusions

Conclusions drawn from the comparison to the predicate device and the nonclinical testing demonstrate that the GrayDuck Stent is as safe, as effective, and performs as well as or better than the predicate device.