DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 8, 2016

Bionix Development Corporation
% James Huttner, M.D., Ph.D.
Vice President, Product Development
5154 Enterprise Blvd.
TOLEDO OH 43612

Re: K153270
Trade/Device Name: TruGuard Custom Tongue and Jaw Positioner
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: February 25, 2016
Received: March 1, 2016

Dear Dr. Huttner:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

B. **Revised Indications for Use :**

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)*
K153270

Device Name
TruGuard Custom Tongue and Jaw Positioner

Indications for Use *(Describe)*
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 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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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

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**Appended Documents:**

**A. Revised 510(k) Summary:**

# 510(k) Summary:

Corporate Office
5154 Enterprise Blvd., Toledo, Ohio 43612

**Date of Application:** 11-4-2015

**Manufacturer:** Bionix Development Corporation
5154 Enterprise Blvd.
Toledo, Ohio 43612

**Contact Information:** James Huttner M.D., Ph.D.
Vice President, New Product Development
Phone: (419) 727-8421
Fax: (419) 727-4430
Email: jhuttner@bionix.com

**Trade Name:** TruGuard Custom Tongue and Jaw Positioner

**Common Name:** Bite Block (positionable)

**Classification Name:** Accessory to Accelerator, Linear, Medical (Per CFR section 892.5050)

**Intended Use:**

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 the treatment of cancer and other diseases.

**Predicate Devices:**

1. Dental Tray for use with the Gill-Thomas- Cosman Relocatable Head Holder, a stereotactic head holder (for LINAC-based stereotactic radiotherapy), manufactured and legally sold by Integra, Plainsboro, NJ. This product is listed under regulation number 892.5050, Accessory to Accelerator, Linear, Medical

and is classified as a Class II device. This product has been approved for sale under K962155.

**Device Description:**

1. **Overview:**

This pre-market notification is being submitted in good faith in an effort to satisfy the requirements of the FDAMA guidelines. Additionally, the FDA does not have any voluntary standards for this device and no standards have been applied.
The TruGuard Custom Tongue and Jaw Positioner from Bionix Development Corporation has been designed using the design control procedures of the Bionix Quality System in compliance with the Good Manufacturing Practice (GMP) Quality System Regulations of the FDA/CDRH. This pre-market notification will draw information from the Design History File for this device and format it for efficient review.

2. **Device Design and Principles of Operation.**

Patients undergoing external beam radiation therapy for the treatment of oral cancer have unique requirements for positioning. Avoiding irradiation of non-involved structures such as tongue and buccal mucosa are critical, as is shielding tissue from secondary low-energy backscatter emissions resulting from high energy photons striking metal fillings and dentures.
The TruGuard Custom Tongue and Jaw Positioner from Bionix is designed to provide reproducible opening of the jaw to multiple pre-set angles, with an optional tongue depressor to move the tongue out of the treatment field. It also provides shielding against secondary low-energy backscatter radiation emitted from metal fillings and bridgework.
The TruGuard Custom Tongue and Jaw Positioner consists of two dental bite trays composed of rigid plastic and connected at the base of their arcs in a bi-valve fashion so as to allow the upper and lower bite trays to open and close in similar fashion as the upper and lower jaws of the patient. The two bite trays are each lined with an insert of low-temperature EVA (ethylene vinyl acetate) thermoplastic material similar to that used in commercial mouth guards. Projections on the lower and upper bite trays mate securely to a plastic indexing tab component that has holes at pre-set locations. When the plastic indexing tab is joined to the upper and lower bite trays the jaw is held open at pre-set angles, depending on the hole selected. This allows the mouth to be positioned and repositioned as needed, and ensures unrestricted air flow to the patient. An optional tongue depressor interlocks with the lower bite tray to restrict the tongue position to the lower portion of the oral cavity.
To use the TruGuard Custom Tongue and Jaw Positioner to position a patient, the following steps are taken:

1. The TruGuard Custom Tongue and Jaw Positioner is placed in hot water to soften the EVA Inserts. The patient then bites down to create dental impressions of their teeth. This allows accurate repositioning of the dental trays between treatments.

2. The tongue depressor is locked into place on the lower bite tray, if indicated.

3. The plastic indexing tab is aligned over the projections on the bite trays and locked into place, holding the mouth at the desired open angle.

4. A standard low-melt thermoplastic face mask is formed over the patient's head with the TruGuard Custom Tongue and Jaw Positioner in place. The upper bite tray of the TruGuard has two threaded posts that can be pushed through the low-melt thermoplastic while it is still soft and pliable. After the low-melt thermoplastic mask cools and hardens, a soft spacer is fitted over the posts and retaining nuts are then screwed onto the posts so as to "sandwich" the low-melt thermoplastic mask between the TruGuard Custom Tongue and Jaw Positioner (on the inside of the mask) and the retaining nuts (on the outside of the mask), holding the TruGuard Custom Tongue and Jaw Positioner in position.

5. After the treatment session, the TruGuard Custom Tongue and Jaw Positioner may be detached from the face mask and cleaned and stored until the next therapy session. The individualized nature of the dental impressions ensure that a particular TruGuard Custom Tongue and Jaw Positioner cannot be used for any other patient.

**Comparison to Predicate Device(s):**

The TruGuard Custom Tongue and Jaw Positioner from Bionix Development Corporation is similar in design and function to existing bite block systems currently in use as accessories to radiation therapy systems.

One of those systems is K962155, the Dental Tray for use with the Gill-Thomas-Cosman Relocatable Head Holder manufactured and legally sold by Integra, Plainsboro, NJ. The Dental Tray holds an impression of the upper teeth, and is part of the GTC Relocatable Head Holder in stereotactic collimated beam, computer planned, LINAC (linear accelerator) based treatment. The Dental Tray holds the dental impression and allows repeat positioning of the stereotactic frame at the same location.

The Dental Tray for the GTC Relocatable Head Holder uses standard dental impression material to create the impression of the upper teeth. One example of commercially available dental impression material is Vinyl Polysiloxane,

tradename Reprosil®. Reprosil® is a hydrophilic vinyl polysiloxane impression material that provides excellent dimensional accuracy and stability for a variety of crown, bridge and edentulous impressions. It forms a putty-like material that is pressed into the GTC Dental Tray; the patient then bites down to form an impression of the upper teeth, then the material is allowed to harden. Once hardened, the GTC Dental tray allows for accurate patient repositioning for each external radiotherapy treatment.

The following table has been prepared comparing the similarities and differences of the Dental Tray for the GTC Relocatable Head Holder and the TruGuard Custom Tongue and Jaw Positioner.

**Table 1**
**Comparison of Substantial Equivalence**
**Dental Tray for Use with the Gill-Thomas-Cosman (GTC) Relocatable Head Holder System (Integra) and TruGuard Custom Tongue and Jaw Positioner (Bionix Development Corporation)**

| Attribute | Dental Tray for use with the Gill-Thomas-Cosman Relocatable Head Holder | Bionix TruGuard Custom Tongue and Jaw Positioner |
|---|---|---|
| **Intended Use** | **Holds a dental impression to allow repeat positioning of a patient receiving external beam radiation therapy** | **Repeat positioning and immobilization of patients receiving external beam radiation therapy** |
| **Reproducible Patient Positioning** | **Yes** | **Yes** |
| **FDA Classification** | **Class II** | **Class II** |
| **Composition** | **Molded Plastic Dental Tray (Attaches to Metal GTC Frame)** | **Molded Plastic** |
| **Dental Impression Material** | **Dental Impression Material (Vinyl Polysiloxane )** | **Moldable EVA Thermoplastic** |
| **Dual Bite Trays** | **No (Upper Bite Tray Only)** | **Yes** |
| **Allows for Open Jaw Positioning** | **No** | **Yes** |
| **Positions the Tongue** | **No** | **Yes** |
| **Attaches to Face Mask** | **No** | **Yes** |
| **Provides Shielding from Backscatter Radiation** | **No Data** | **Yes** |
| **MRI Safe** | **Yes (Dental Tray Only)** | **Yes** |

**Bench Testing:**

Bench testing was performed on the TruGuard Custom Tongue and Jaw Positioner to determine shielding efficacy against backscatter radiation produced by high-energy photons striking metal fillings and bridgework.

Test subjects were exposed to a 6 MeV high energy photon beam, and the backscatter radiation dose was evaluated by measuring the exposure density of industry standard Gafchromic EBT3 film placed adjacent to the test subject. Results were plotted as “Dose Enhancement Ratio” vs. “Position Across Teeth”. The “Dose Enhancement Ratio” was defined as the backscatter radiation dose produced by the test subject divided by a “Baseline” dose (backscatter radiation produced with no test subject in the photon beam).
Shielding efficacy was indicated by the Dose Enhancement Ratio. Values greater than 1 indicate an increased dose of backscatter radiation to the patient and a poor shielding effect, whereas a ratio of 1 indicates total shielding with no backscatter radiation dose delivered to the patient.
Figure 13 shows the results of this bench testing using various combinations of the phantom (teeth with amalgam fillings) and TruGuard components. The plot showing the Dose Enhancement Ratio of only the phantom (teeth + filling) in the photon beam shows a spike over all teeth, with the greatest Dose Enhancement over the center tooth having the metal amalgam filling, as expected. The plots showing the Dose Enhancement Ratios for the phantom when covered by the EVA insert material only, the Dental Tray material only, and the assembled TruGuard are effectively 1.0, showing near total shielding efficacy of the TruGuard device in shielding against backscatter radiation.

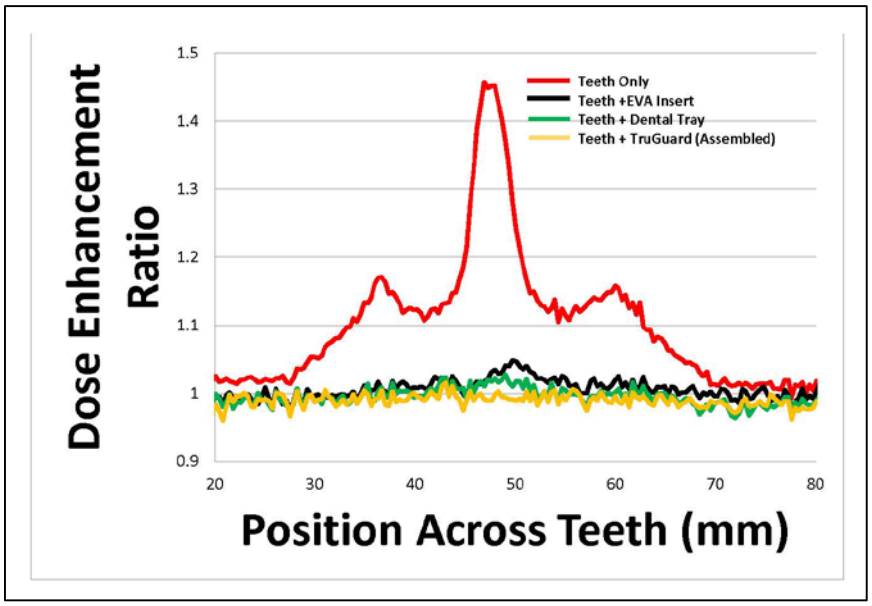


**Figure 13**
**Dose Enhancement Ratio Plot**
**Demonstrating TruGuard Shielding**

**Conclusion:**

The similarity of design, features, composition, and function indicate that TruGuard Custom Tongue and Jaw Positioner from Bionix Development Corporation will perform as well as the legally marketed Dental Tray for use with the Gill-Thomas- Cosman Relocatable Head Holder, manufactured and legally sold by Integra, Plainsboro, NJ for the intended use 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.