Genoray Co., Ltd.
% Ms. Kaitlynn Min
Business Development Manager
Genoray America, Inc.
147 E. Bristol Lane
ORANGE CA 92865

September 16, 2020

Re: K200469
Trade/Device Name: PAPAYA 3D Premium & PAPAYA 3D Premium Plus
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS, MUH
Dated: August 12, 2020
Received: August 13, 2020

Dear Ms. Min:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200469

Device Name
PAPAYA 3D Premium & PAPAYA 3D Premium Plus

Indications for Use *(Describe)*
The X-ray unit system is a diagnostic imaging system which consists of multiple image acquisition modes; panoramic, cephalometric, and CBCT (Cone Beam Computed Tomography). X-ray unit system is used for dental radiographic examination and diagnosis of teeth, jaw, oral structures and skull. The device is to be operated and used dentists and other legally qualified professionals.

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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Exhibit 5 510(k) Summary K200469

Date of Summary Preparation: February 21, 2020

1. Submitter and US Official Correspondent

Submitter: GENORAY Co., Ltd.
Address: 512, 560, Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-Do, Korea
Telephone No.: +82-31-740-4100
Fax: +82-31-740-4195

Official Correspondent (U.S): Kaitlynn Min - Business Manager
Correspondent: GENORAY America Inc.
Address: 147 E. Bristol Lane, Orange, CA 92865 USA
Telephone No.: +1-855-436-6729
Fax: +1-714-786-8919
Email: kaitlynn@genorayamerica.com

2. Establishment Registration Number

: 3005843418

3. Device Information

- **Product/Trade Name:** PAPAYA 3D Premium & PAPAYA 3D Premium Plus
- **510(k) Number:** K200469
- **Common Name:** Computed Tomography X-ray System
- **Classification Name:** Computed Tomography X-ray System
- **Classification panel:** Radiology
- **Regulation number:** 21 CFR 892.1750
- **Device Class:** Class II
- **Primary Product code:** OAS
- **Secondary product code:** MUH

4. Predicate Device (Equivalent Legally Marketed Device)

PAPAYA 3D Plus (K150354, GENORAY Co., Ltd)

5. Description of the Device

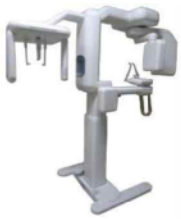
The proposed device PAPAYA 3D Premium & PAPAYA 3D Premium Plus the computed tomography x-ray system which consists of image acquisition modes; panorama, cephalometric, and computed tomography. The difference between PAPAYA 3D Premium and PAPAYA 3D Premium Plus is only optional of the cephalometric detector. It designed for dental radiography of the oral and craniofacial anatomy such as teeth, jaws and oral structures. The device with cephalometric detector is named PAPAYA 3D Premium Plus and the device without cephalometric detector is named PAPAYA 3D Premium.

The proposed device are composed of flat panel x-ray detectors which are based on CMOS, and TFT detector types and divided in to CT, panoramic and cephalometric radiography, and x-ray tube. CMOS, and TFT detectors are used to capture scanned image for obtaining diagnostic information for craniofacial surgery or other treatments. And it also provides 3D diagnostic images of the anatomic structures by acquiring 360°rotational image sequences of oral and craniofacial area.

6. Indications for use (intended use)

The X-ray unit system is a diagnostic imaging system which consists of multiple image acquisition modes; panoramic, cephalometric, and CBCT (Cone Beam Computed Tomography). X-ray unit system is used for dental radiographic examination and diagnosis of teeth, jaw, oral structures and skull. The device is to be operated and used by dentists and other legally qualified professionals.

7. Substantial equivalence chart

Criteria	Proposed Device		Predicate Device
Name	PAPAYA 3D Premium & PAPAYA 3D Premium Plus		PAPAYA 3D Plus
Manufacturer	GENORAY Co., Ltd.		GENORAY Co., Ltd.
510(k) No.	K200469		K150354
Figure	 <PAPAYA 3D Premium>	 <PAPAYA 3D Premium Plus>	
Indications for use	The X-ray unit system is a diagnostic imaging system which consists of multiple image acquisition modes; panoramic, cephalometric, and CBCT (Cone Beam Computed Tomography). X-ray unit system is used for dental radiographic examination and diagnosis of teeth, jaw, oral structures and skull. The device is to be operated and used by dentists and other legally qualified professionals.		PAPAYA 3D Plus is a digital panoramic, cephalometric and tomographic extra-oral X-ray system, indicated for use in: (i) Producing panoramic X-ray images of the maxillofacial area, for diagnostic examination of dentition (teeth), jaws and oral structures; and (ii) Producing radiographs of jaws, parts of the skull and carpus for the purpose of cephalometric examination, when equipped with the cephalometric arm; (iii) Producing tomographic images of the oral and maxillofacial structure, for diagnostic examination of dentition (teeth), jaws, oral structures and some cranial bones if equipped with CBCT option. The system accomplishes tomographic exam by acquiring a 360-degree rotational X-ray sequence of images and reconstructing a three-dimensional matrix of the examined volume, producing two-dimensional views of this volume and displaying both two dimensional images and three-dimensional renderings
Performance Specification	Panoramic Computed tomography	Panoramic Cephalometric Computed tomography	Panoramic Cephalometric Computed tomography
Input Voltage	100-240 V~, 50/60Hz	100-240 V~, 50/60Hz	100-120 V~, 50/60Hz
Tube Voltage	60-90 kV	60-90 kV	60-90 kV
Tube Current	4-12 mA	4-12 mA	4-12 mA
Focal Spot Size	0.5 mm	0.5 mm	0.5 mm
Exposure Time	Panorama: max 17 sec. CBCT: max 24sec	Panorama: max 17 sec. Cephalometric: max 15.5 sec. CBCT: max. 24sec	Panorama: max 17sec. Cephalometric: max 12sec. CBCT: max. 15sec.
Image Receptor	**Panoramic image receptor:** - Extor-P (K150354) **CBCT image receptor:** - DualRay-S (K150354) - FXDD-0606CA (K182805) - FXDD-0909GA	**Panoramic image receptor:** - Extor-P (K150354) **Cephalometric image receptors:** - Extor-C (K150354) - FXDD-1012CA **CBCT image receptors:** - DualRay-S (K150354) - FXDD-0606CA (K182805) - FXDD-0909GA	**Panoramic image receptor:** - Extor-P **Cephalometric image receptor:** - Extor-C **CBCT image receptor:** - DualRay-S
Image processing Software	Triana (K103182), Theia (optional)	Triana (K103182), Theia (optional)	Triana (K103182)
Result	The proposed device, PAPAYA 3D Premium & PAPAYA 3D Premium Plus, was developed from the predicate device PAPAYA 3D Plus (K150354), and modifications are changing of input power, addition of detector, addition of image processing software, and minor external design changes. Accordingly, the characteristics of the proposed device is identical or similar to those of the predicate device regarding X-ray generation device characteristics including tube voltage, tube current, focal spot size. First of all, the input voltage (power rating) of Predicate device was 100-120V~, 50/60Hz, however due to changes of the power board, proposed device is available to 100-240V~, 50/60Hz. Second, the proposed device has same detector with predicate device which are DualRay-S (CT detector), Extor-C (cephalometric detector), Extor-P (panoramic detector), and additionally proposed device has FXDD-1012CA (cephalometric detector), FXDD-0606CA (CT detector), and FXDD-0909GA (CT detector). However cephalometric detectors (Extor-C, and FXDD-0909GA) are only available for PAPAYA 3D Plus and PAPAYA 3D premium Plus. Overall PAPAYA 3D Premium has one option for panoramic detector, and three types of CT detectors and PAPAYA 3D Premium Plus has one option for panoramic detector, two options for cephalometric detectors, and three types of CT detectors. Additionally, the FXDD-0606CA detector has been cleared under K182805, RCT800. Third, the predicate device can be used with image processing software, Triana, only. The proposed device can be used with same software, Triana, or newly developed image processing software, Theia. The difference between Triana and Theia is only UI, and the Theia was developed for marketing purpose only. Theia was validated throughout EN 62304:2006/AC: 2008. \ Fourth, the minor external design of the proposed device has changed comparing predicate device. The patient supporting area can be foldable, the emergency switch on the patient supporting area has been moved from downside to upside, the storage box has been added, and the plastic enclosure design has changed.		

8. Safety, EMC and Performance data comparison to Predicate

Since electrical and mechanical performance of the proposed device has changed, such as input voltage, additional detector options, additional image processing software option, external design, comparing to predicate device the safety and EMC test was performed throughout IEC 60601-1, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-2-63, and IEC 60601-1-2 to minimize electrical, mechanical and radiation hazards.

For the additional software, Theia, saves the patient image data and offers an inquiry function in addition, supports the image processing function intended to obtain images by using the PAPAYA 3D Premium & PAPAYA 3D Premium Plus and detector options for diagnosis. And has been validated according to NEMA PS 3.1-3.20. DICOM, FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical devices", FDA Guidance "Guidance for the content of premarket submissions for management of cyber security" to ensure substantial equivalence. The software, Theia, was considered as a "moderate" level of concern, since a failure or latent flaw in the software would not directly result in serious injury or death to the patient or operator.

For the newly added CBCT image receptor (FXDD-0909GA), and Cephalometric image receptor (FXDD-1012CA) it has been validated according to FDA "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" as clinical considerations, and the clinical images were evaluated by the US board-certified oral surgeon. Throughout the evaluation by oral surgeon, the image quality of the proposed device with newly added detectors are well enough to diagnosable and meet its indications for use.
Furthermore, the imaging performance of newly added CBCT image receptor (FXDD-0909GA) such as gantry positioning accuracy, In-plane uniformity, Spatial Resolution, Reconstruction section thickness, Noise, Contrast to Noise Ratio, Geometric Distortion, and Metal Artifacts and Cephalometric image receptor (FXDD-1012CA) such as Line pair resolution, and Low contrast resolution was tested with phantoms to validate its performance. The detail information about the clinical image evaluation can be found in the "Attachment X Evaluation of PAPAYA 3D Premium & PAPAYA 3D Premium Plus images" and the imaging performance test report can be found in the "Attachment IX Solid State X-ray Imaging Device".

Overall the modifications from the predicate device were completed in accordance GENORAY quality management system design controls. A risk analysis, validation testing and Declaration of Conformity to Design Controls were submitted to support the substantial equivalence of the modified proposed device. The results of them indicate that the modified proposed device is as safe and effective as the predicate devices.

9. Conclusion

Proposed device has the same indication for use as the predicate device. And there have been no changes that impact either the fundamental technology or the indications for use. The proposed device with modifications outlined in this Premarket Notification is substantially equivalent to the currently commercially available predicate device.