GENORAY Co., Ltd.
℅ Kaitlynn Min
Business Development
GENORAY America Inc.
147 E. Bristol Lane
ORANGE CA 92865

May 19, 2022

Re: K220392
Trade/Device Name: PAPAYA 3D & PAPAYA 3D Plus
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: February 17, 2022
Received: February 18, 2022

Dear Kaitlynn 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

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT 8B: Division of Radiological Imaging
and Electronic Products
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)*
K220392

Device Name
PAPAYA 3D & PAPAYA 3D Plus

Indications for Use *(Describe)*
PAPAYA 3D & PAPAYA 3D Plus are digital panoramic, cephalometric and tomographic extra-oral X- ray systems, 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 (Only for PAPAYA 3D Plus);
(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 systems accomplish 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.

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

Date of Summary Preparation: Feb 16, 2022

1. Submitter and US Official Correspondent

Submitter: GENORAY CO., Ltd.
Address: 512, 560, Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-Do, KOREA

Official Correspondent (U.S): Kaitlynn Min - Business Manager
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2. Establishment Registration Number

3005843418

3. Device Information

Trade / Proprietary Name : PAPAYA 3D & PAPAYA 3D Plus
Device Class : Class Ⅱ
Regulation Number : 21 CFR 892.1750
Classification Name / Product Code: Computed Tomography x-ray System / OAS

4. Predicate Device (Equivalent Legally Marketed Device)

Trade / Proprietary Name : PAPAYA 3D Plus (K150354)
Device Class: Class II
Regulation Number : 21 CFR 892.1750
Classification Name / Product Code: Computed Tomography x-ray System / OAS

5. Reference Device (Equivalent Legally Marketed Device)

Trade / Proprietary Name : Triana (K103182)
Device Class: Class II
Regulation Number : 21 CFR 892.2050
Classification Name / Product Code: System, Image Processing, Radiological / LLZ
Indications for Use(IFU)
: Triana is intended for use as a software package which obtains medical images from CT, Cephalometric / Panoramic X-ray system & etc., stores those and provides 3D visualization, 2D analysis, various MPR(Multi-Planar Reconstruction) functions for further rapid and precise diagnosis.

6. Description of the Device

PAPAYA 3D & PAPAYA 3D Plus are diagnostic imaging system which consists of multiple image acquisition modes; panorama, cephalometric, and computed tomography. Also, PAPAYA 3D & PAPAYA 3D Plus are designed for dental radiography of the oral and craniofacial anatomy such as teeth, jaws and oral structures. The difference between PAPAYA 3D & PAPAYA 3D Plus is only optional of the cephalometric detector. Without cephalometric detector, we name model PAPAYA, and with cephalometric detector, we name model PAPAYA Plus. Due to this difference, the cephalometric image acquisition function applies only to PAPAYA 3D Plus, not to PAPAYA 3D.

PAPAYA 3D Plus is equipped with extra-oral flat panel x-ray detectors which is based on CMOS digital X-ray detector and has CT, panoramic and cephalometric radiography with an extra-oral x-ray tube. CMOS Flat panel 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.

The differences from predicate device (K150354) are change of power voltage, addition of image processing software (Theia, Triana).

First of all, the input voltage (power rating) of predicate device was 100-120V~, 50/60Hz. However due to change of the power board, proposed device is available to 100-240V~. 50/60Hz. Due to this power specification change, critical components change was verified via safety/EMC test report performed by CSA and SGS according to IEC 60601-1 (3.0 ed), IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-63.

Second, , the proposed device can be used with image processing software, Triana(K103182) or Thiea. Triana (K103182) and Theia are image processing software that processes image acquired through PAPAYA 3D & PAPAYA 3D Plus. The two software uses not only the purpose of use, but also acquires and stores the image, and Inquires and processes the acquired image (deletion, enlargement, reduction, rotation, distance and angle measurement, drawing information in the image, 3D image reconstruction, etc.), it is the same in that it has the function to finally transmit to the DICOM Server. However, in Theia, by rearranging the configuration within the UI to improve the user's convenience, there is only a visual difference between Triana and Theia. Triana and Theia were validated throughout IEC 62304:2006/AC: 2008.

7. Indications for use (intended use)

PAPAYA 3D & PAPAYA 3D Plus are digital panoramic, cephalometric and tomographic extra-oral X- ray systems, 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 (Only for PAPAYA 3D Plus);
(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 systems accomplish 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.

8. Substantial equivalence chart

Criteria	Proposed device		Predicate Device	
Name	PAPAYA 3D & PAPAYA 3D Plus		PAPAYA 3D Plus	
Manufacturer	GENORAY Co., Ltd.		GENORAY Co., Ltd.	
510(k) No.	-		K150354	
Figure				
	<PAPAYA 3D>	<PAPAYA 3D Plus>	<PAPAYA 3D>	<PAPAYA 3D Plus>
Indications for use	PAPAYA 3D & PAPAYA 3D Plus are digital panoramic, cephalometric and tomographic extra-oral X- ray systems, 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 (Only for PAPAYA 3D Plus); (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 systems accomplish 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.		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 Computed tomography	Panoramic Cephalometric Computed tomography
3D Technology		Cone beam Computed tomography	Cone beam Computed tomography	Cone beam Computed tomography	Cone beam Computed tomography
CT FOV (D X H)		14x14,14x8,8x8,7x7,4x4 cm	14x14,14x8,8x8,7x7,4x4 cm	14x14,14x8,8x8,7x7,4x4 cm	14x14,14x8,8x8,7x7,4x4 cm
Input Voltage		100-240 V~, 50/60Hz	100-240 V~, 50/60Hz	100-120 V~, 50/60Hz	100-120 V~, 50/60Hz
Tube Voltage		60-90 kV	60-90 kV	60-90 kV	60-90 kV
Tube Current		4-12 mA	4-12 mA	4-12 mA	4-12 mA
Focal Spot Size		0.5 mm	0.5 mm	0.5 mm	0.5 mm
Total Filtration		2.8 mm Al (Canon tube)	2.8 mm Al (Canon tube)	2.5 mm Al (CEI tube) 2.8 mm Al (Canon tube)	2.5 mm Al (CEI tube) 2.8 mm Al (Canon tube)
Exposure Time		Panorama : max 17 sec CT : max 15 sec	Panorama : max 17 sec Cephalo : max 15.5 sec CT : max 15 sec	Panorama : max 17 sec CT : max 15 sec	Panorama : max 17 sec Cephalo : max 15.5 sec CT : max 15 sec
Image Receptor		Panoramic : CMOS FPD CT : CMOS FPD	Panoramic : CMOS FPD Cephalo : CMOS FPD CT : CMOS FPD	Panoramic : CMOS FPD CT : CMOS FPD	Panoramic : CMOS FPD Cephalo : CMOS FPD CT : CMOS FPD
Image processing Software	S/W	Triana (K103182)	Theia	-	-
	Intended Use	Triana and Theia are intended for use as a software package software which obtains medical images from CT, Cephalometric / Panoramic X-ray system & etc., stores those and provides 3D visualization, 2D analysis, various MPR (Multi-Planar Reconstruction) functions for further rapid and precise diagnosis.			

	General Function	- obtaining medical images - storing medical images - Inquires and processes the acquired image (deletion, enlargement, reduction, rotation, distance and anglemeasurement, drawing information in the image) - 3D visualization - 2D analysis - various MPR (Multi-Planar Reconstruction)	- obtaining medical images - storing medical images - Inquires and processes the acquired image (deletion, enlargement, reduction, rotation, distance and anglemeasurement, drawing information in the image) - 3D visualiziation - 2D analysis - various MPR (Multi-Planar Reconstruction)		
Result		The proposed devices, PAPAYA 3D & PAPAYA 3D Plus, are developed from the predicate device PAPAYA 3D Plus (K150354), and modifications are changing of input power, addition of image processing software. First of all, the input voltage (power rating) of predicate device was 120V~, 60Hz. However due to change of the power board, proposed device is available to 100-240V~. 50/60Hz. Due to this power specification change, critical components change was verified via safety/EMC test report performed by CSA and SGS according to IEC 60601-1 (3.0 ed), IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-63. Second, the proposed device can be used with image processing software, Triana or Thiea. The difference between Triana and Theia is only UI, and the Theia was developed for marketing purpose only. Triana and Theia were validated throughout IEC 62304:2006/AC: 2008. Third, Theia is a newly developed software after the release of Triana, but as can be seen from the table above, both Triana and Theia can be used for PAPAYA 3D & PAPAYA 3D Plus, and the technical characteristics and applications, including the Intended Use, are essentially the same. can be judged to be equivalent. Also, the general functions of both software are the same overall. The General function is the same for both Theia and Triana. However, Theia added 3D TMJ Screen (a function to view the TMJ part separately) and Airway screen (a function to indicate the airway), which are detailed functions within the 3D visualization function, to improve the user's convenience in the functions of Triana.		

9. Safety, EMC and Performance data comparison to Predicate

Device Safety, EMC and Performance data is same to predicate device which has been established in 510(k) submission K150354 as below. All test results were satisfactory

- Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1, IEC 60601-1-3, and IEC 60601-2-63 were performed.

- EMC testing was conducted in accordance with standard IEC 60601-1-2.

- Acceptance test according to standard IEC 61223-3-4 and IEC 61223-3-5 were performed.

- FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" was performed for each detector of PAPAYA 3D Plus.
  The existing detector test results are as follows.
  The tests include the MTF, DQE and the dynamic range of the panoramic sensor and the cephalometric sensor. Both the MTF of the two detectors shows the resolution more than 80% at 2lp / mm and the DQE of them shows the performance of about 80% at 0lp / mm. The dynamic range of them shows more than 72dB.
  And, the additional detector test results are as follows.
  The tests include the MTF, DQE and the dynamic range of the panoramic sensor, the cephalometric sensor and the CT sensor. The MTF of the detectors shows the resolution more than 60% at 1lp / mm and the DQE of them shows the performance of about 70% at 0lp / mm. The dynamic range of them shows more than 72dB.
  Based on the Non-Clinical Test results, even though the pixel size and active area of the SSXI detectors are different, the diagnostic image quality of sensors is similar to that of the predicate device and there is no significant difference in efficiency and safety.
  Please refer to Attachment X. Solid State X-ray imaging Device.

- PAPAYA 3D Plus meets the EPRC standards (21 CFR 1020.30. 31. 33)

- PAPAYA 3D Plus also meets the provisions of NEMA PS 3.1-3.18. Digital Imaging and Communications in Medicine (DICOM) Set.

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014

- Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, Document issued on: May 11, 2005 Medical Devices, Document issued on: May 11, 2005

- Guidance for Industry and Food and Drug Administration Staff Pediatric Information for X-ray Imaging Device Premarket Notifications, November 2017

- PAPAYA 3D Plus uses Triana or Thiea as the image viewer. The difference between Triana and Theia is only UI, and the Theia was developed for marketing purpose only. Triana and Theia were validated throughout IEC 62304:2006/AC: 2008.
  In this document, only the validation report of the Theia except for Triana (K103182), which is currently on the market. Software validation report was conducted as recommended by FDA's Guidance document "Guidance for off-the-shelf Software Use in Medical Devices" The OTS Software, Triana in PAPAYA 3D Plus represents a Minor Level of Concern since failures or latent design flaws would not be expected to result in any injury to the patient or operator.

- PAPAYA 3D Plus was tested for safety and effectiveness related in Clinical Evaluation report.

10.Conclusion

In reference to the comparison information provided in substantial equivalence chart, there the proposed device and the predicate device have no changes that impact either the fundamental technology or the indication for use. And most of functions and electronic features of the proposed device are similar with the predicate device. We believe that the PAPAYA 3D & PAPAYA 3D Plus are safe and effective as predicate device, and have no new indication for use. Thus PAPAYA 3D & PAPAYA 3D Plus are substantially equivalent to predicate device.