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

May 19, 2022

Re: K220423
Trade/Device Name: PAPAYA & PAPAYA Plus
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
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)*
K220423

Device Name
PAPAYA & PAPAYA Plus

Indications for Use *(Describe)*
PAPAYA & PAPAYA Plus are digital extraoral source X-ray system intended to produce panoramic and cephalometric(option) images of the oral and craniofacial anatomy for a precise treatment planning in adult and pediatric care. The system is used for dental & skull radiographic examination and diagnosis of teeth, jaw, oral structure, and skull by exposing an X-ray image receptor to ionizing radiation, with a digital imaging capability for taking both panoramic and cephalometric images. And This system can be equipped cust(Tomographic) option, which is capable of taking cross-sectional radiographic images. These images provide dimensional information for dental implant planning and information about location of impacted teeth.

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.

Exhibit 5 510(k) Summary

Date of Summary Preparation: Feb 16, 2022

1. Submitter and US Official Correspondent

Submitter : GENORAY Co., Ltd.
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Official Correspondent (U.S): Kaitlynn Min - Business Manager
Correspondent : GENORAY America Inc.
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Telephone No. : +1-855-436-6729
Fax : +1-714-786-8919
Email : kaitlynn@genorayamerica.com

2. Establishment Registration Number

: 3005843418

3. Device Information

Trade Name / Proprietary Name: PAPAYA & PAPAYA Plus
Common Name: Digital X-ray Imaging System
Classification Name / Product Code: Extraoral Source X-ray System / MUH
Regulation Number: 21 CFR 872.1800
Device Class: Class II

4. Predicate Device (Equivalent Legally Marketed Device)

Trade Name / Proprietary Name: PAPAYA Plus (K141700, GENORAY Co., Ltd)
Common Name: Digital X-ray Imaging System
Classification Name / Product Code: Extraoral Source X-ray System / MUH
Regulation Number: 21 CFR 872.1800
Device Class: Class II

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

The proposed devices PAPAYA & PAPAYA Plus are diagnostic imaging system which consists of multiple image acquisition modes; panorama and cephalometric. The difference beteween PAPAYA & PAPAYA Plus is only optional of the cephalometric detector. (Without cephalometric detector, we model named PAPAYA, and with cephalometric detector, we model named PAPAYA Plus.)

The proposed devices have the CUST imaging option which is used to reconstruct tomographic images from a set of pre-acquired projection radiographic images of the object.

The differences from predicate device(K141700) are change of power voltage, addition of image processing software(Theia, Triana).

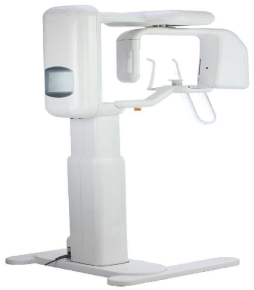
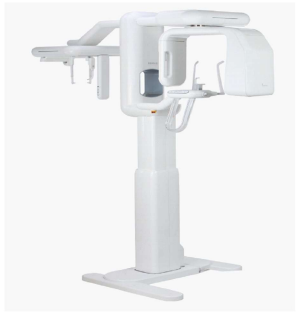
First of all, the input voltage (power rating) of predicate device was 120V~, 60Hz. However due to change of the power board, proposed device is available to 100-240V~. 50/60Hz. Due to this power specification change, critical components change was verified via safety/EMC test report performed by CSA 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(K103182) or Thiea. Triana (K103182) and Theia are image processing software that processes image acquired through PAPAYA & PAPAYA 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

PAPAYA & PAPAYA Plus are a digital extraoral source X-ray system intended to produce panoramic and cephalometric(option) images of the oral and craniofacial anatomy for a precise treatment planning in adult and pediatric care. The system is used for dental & skull radiographic examination and diagnosis of teeth, jaw, oral structure, and skull by exposing an X-ray image receptor to ionizing radiation, with a digital imaging capability for taking both panoramic and cephalometric images. And this system can be equipped CUST (Tomographic) option, which is capable of taking cross-sectional radiographic images. These images provide dimensional information for dental implant planning and information about location of impacted teeth

7. **Substantial equivalence chart**

Criteria	Proposed device		Predicate Device	
Name	PAPAYA & PAPAYA Plus		PAPAYA Plus	
Manufacturer	GENORAY Co., Ltd.		GENORAY Co., Ltd.	
510(k) No.	-		K141700	
Figure				
	<PAPAYA>	<PAPAYA Plus>	<PAPAYA>	<PAPAYA Plus>
Indications for use	PAPAYA & PAPAYA Plus are digital extraoral source X-ray system intended to produce panoramic and cephalometric(option) images of the oral and craniofacial anatomy for a precise treatment planning in adult and pediatric care. The system is used for dental & skull radiographic examination and diagnosis of teeth, jaw, oral structure, and skull by exposing an X-ray image receptor to ionizing radiation, with a digital imaging capability for taking both panoramic and cephalometric images. And This system can be equipped cust(Tomographic) option, which is capable of taking cross-sectional radiographic images. These images provide dimensional information for dental implant planning and information about location of impacted teeth.		PAPAYA & PAPAYA Plus are digital extraoral source X-ray system intended to produce panoramic and cephalometric(option) images of the oral and craniofacial anatomy for a precise treatment planning in adult and pediatric care. The system is used for dental & skull radiographic examination and diagnosis of teeth, jaw, oral structure, and skull by exposing an X-ray image receptor to ionizing radiation, with a digital imaging capability for taking both panoramic and cephalometric images. And This system can be equipped cust(Tomographic) option, which is capable of taking cross-sectional radiographic images. These images provide dimensional information for dental implant planning and information about location of impacted teeth.	
Performance Specification	Panoramic	Panoramic and Cephalometric	Panoramic	Panoramic and Cephalometric
Input Voltage	100-240 V~, 50/60Hz	100-240 V~, 50/60Hz	120 V~, 60Hz	120 V~, 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
Exposure Time		Panorama: max 17 sec.	Panorama: max 17 sec. Cephalo : max 12 sec.	Panorama: max 17 sec.	Cephalo : max 12 sec.
Exposure mode		Panorama: Panoramic mode TMJ mode SINUS mode CUST mode	Panorama: Panoramic mode TMJ mode SINUS mode CUST mode Cephalo: Cephalo mode	Panorama: Panoramic mode TMJ mode SINUS mode CUST mode	Panorama: Panoramic mode TMJ mode SINUS mode CUST mode Cephalo: Cephalo mode
Image Receptor		Panoramic sensor : CMOS	Panoramic & cephalometric sensor : CMOS	Panoramic sensor : CMOS	Panoramic & cephalometric sensor : CMOS
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 & PAPAYA Plus, are was developed from the predicate device PAPAYA Plus (K141700), 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 & PAPAYA 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.

8. 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 K141700 as below. All test results were satisfactory.

- Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1, IEC 60601-1-3, , IEC 60601-1-6, IEC 60601-2-63, IEC 62366 and IEC 62304 were performed.

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

- 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

- FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" was performed. The tests include the MTF, DQE and the dynamic range of the panoramic sensor and the cephalometric sensor.

- PAPAYA & PAPAYA Plus also meet the provisions of NEMA PS 3.1-3.20. Digital Imaging and Communications in Medicine (DICOM) Set.

- PAPAYA & PAPAYA Plus were tested for safety and effectiveness in Clinical Evaluation Report and bench.

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 indication for use. The proposed device with modification outlined in this Premarket Notification is substantially equivalent to the currently commercially available predicate device.