K130419

NOV - 6 2013

Exhibit 5 510(k) Summary

Date of Summary Preparation: January 18, 2013

1. Submitter and US Official Correspondent

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Telephone No.:	+82-31-740-4100
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Official Correspondent (U.S): Jae Kim - Business Manager

Correspondent :	GENORAY America Inc.
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Telephone No.:	855-436-6729
Fax:	714-786-8919
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2. Establishment Registration Number

3005843418

3. Device Information

Proprietary/Trade Name: PAPAYA Plus
Common/Usual Name: Digital X-ray Imaging System
Classification Name: System, X-ray, Extraoral Source, Digital
Product Code: MUH
Device Class: Class II per regulation 21 CFR 872.1800

4. Equivalent Legally Marketed Device

< PCH-2500 (PaX-i)>

Manufacturer:	Vatech Co., Ltd.
Device Name:	PCH-2500 (PaX-i)
510(k) Number:	K122155 (Decision Date: Sep 04, 2012)
Classification:	System, X-ray, Extraoral Source, Digital: MUH, Class II per regulation 21 CFR 872.1800

5. Description of the Device

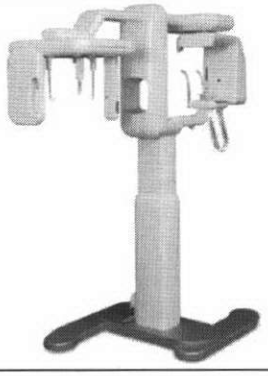
PAPAYA Plus is a diagnostic imaging system which consists of multiple image acquisition modes: panorama and cephalometric. PAPAYA Plus is designed for dental radiography of the oral and craniofacial anatomy. PAPAYA Plus is equipped with extra-oral x-ray detector based on CdTe digital X-ray detector, panoramic & cephalometric radiography with an extra-oral x-ray tube. CdTe digital X-ray detector is used to capture scanned image for obtaining diagnostic information for craniofacial surgery or other treatments. Cephalometric radiography is optional function. It can be choice to use the cephalo function as user's need.

Items \ Product	PAPAYA Plus
Performance Specification	Panoramic and cephalometric
X-ray Source	High Frequency, Stationary tube, 60 ~ 90 kV, 4 ~ 12mA
Focal Spot	0.5mm
Image Detector	CdTe detector - Pixel size: 100um x 100um - Image field: Panoramic&Cephalometric sensor : 240mm x 4.8mm Panoramic sensor : 150mm x 4.8mm
Scan time / exposure time	Standard panorama program (Normal, Average): 12 sec Cephalo (Normal): 8 sec
Power Voltage / Input power	120 V~, 60 Hz, 2.2 kVA
Total filtration	CEI Tube: 2.5mmAl (inherent:0.5mmAl, Added:2.0mmAl) Toshiba Tube: 2.8mmAl (inherent:0.8mmAl, Added:2.0mmAl)
Patient position	Standing
Main body weight	140 kg ± 5%
Dimension (W×H×D mm)	1775.4 × 2312 × 1010 mm

6. Indications for use

PAPAYA Plus is a digital extraoral source X-ray system intended to produce panoramic and Cephalometric 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.

7. Substantial equivalence chart

Name	PAPAYA Plus	PCH-2500 (PaX-i)
Manufacturer	GENORAY Co., Ltd.	Vatech Co., Ltd.
510(k) No.	K130419	K122155
Classification	System, X-ray, Extraoral Source, Digital: MUH, Class II per regulation 21 CFR 872.1800	System, X-ray, Extraoral Source, Digital: MUH, Class II per regulation 21 CFR 872.1800
Figure		
Indications for use	PAPAYA Plus is a digital extraoral source X-ray system intended to produce panoramic and Cephalometric 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.	PCH-2500 (PaX-i) is a digital extraoral source x-ray system intended to take panoramic and cephalometric images of the oral and maxillofacial anatomy to provide diagnostic information for adult and pediatric patients. The device should be operated and used by dentists, x-ray technicians and other professionals licensed by the law of the state in which the device is used.
Performance Specification	Panoramic and cephalometric	Panoramic and cephalometric
Input Voltage	120 V~	100-120 V~
Tube Voltage	60-90 kV	50-90 kV
Tube Current	4-12 mA	4-10 mA
Focal Spot Size	0.5 mm	0.5 mm
Exposure Time	Max. 17 sec	Max. 20.2 sec
Total Filtration	2.5 mmAl (CEI tube) 2.8 mmAl (Toshiba tube)	2.8 mmAl
Pixel Size	Panoramic & cephalometric sensor: 100 x 100 μm	Panoramic & cephalometric sensor: 100 x 100 μm Cephalometric (one shot type) sensor: 127 x 127 μm
Image Receptor	Panoramic & cephalometric sensor : CdTe Sensor	Panoramic & Cephlometric sensor: CMOS Photodiode array Cephalometric sensor(scan type): Amorphous silicon TFT with scintillator

Indications for use, performance specification and technical characteristics of PAPAYA Plus and PCH-2500 (PaX-i) are similar. The primary difference is to offer a CdTe sensor for Panorama and Cephalometric mode of PAPAYA Plus. The Performance data for the CdTe sensor are provided in this submission.
Therefore, PAPAYA Plus is deemed to be substantially equivalent to the predicate device, PCH-2500 (PaX-i) in safety and effectiveness.

8. Safety, EMC and Performance data comparison to Predicate
   - Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1, IEC 60601-1-1, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28, IEC 60601-2-32 and IEC 61223-3-4 were performed.
   - EMC testing was conducted in accordance with standard IEC 60601-1-2.
   - FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" was performed.
   - PAPAYA Plus meets the EPRC standards (21 CFR 1020.30, 31).
   - PAPAYA Plus also meets the provisions of NEMA PS 3.1-3.18, Digital Imaging and Communications in Medicine (DICOM) Set.

   All test results were satisfactory.
   The result of bench and clinical evaluation indicates that the new device is as safe and effective as the predicate devices.

9. Conclusion
   In reference to the comparison information provided in substantial equivalence chart, most of function and electronic feature are similar in both products. We believe that the PAPAYA Plus is safe, effective and substantially equivalent in clinical & technical expect with the predicate devices, PCH-2500 (PaX-i).

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

November 6, 2013

Genoray Co., Ltd.
% Mr. Jae Kim
Business Development Manager
1073 N. Batavia Street
ORANGE CA 92867

Re: K130419
Trade/Device Name: PAPAYA Plus, Digital X-ray Imaging System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: October 03, 2013
Received: October 07, 2013

Dear Mr. Kim:

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.

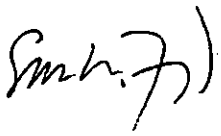
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Janine M. Morris
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130419

Device Name
Digital X-ray Imaging System (Model: PAPAYA Plus)

Indications for Use *(Describe)*
PAPAYA Plus is a digital extraoral source X-ray system intended to produce panoramic and Cephalometric 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*