DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 28, 2016

VATECH Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

Re: K160882
Trade/Device Name: PaX-i3D Green Premium (Model: PCT-90LH)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: September 22, 2016
Received: September 29, 2016

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 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

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)*
K160882

Device Name
PaX-i3D Green Premium (Model: PCT-90LH)

Indications for Use *(Describe)*
PaX-i3D Green Premium (Model: PCT-90LH) is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral anatomy by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the maxillofacial areas for a dental and ENT treatment in adult and pediatric dentistry. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by physicians, dentists, ENT specialist and x-ray technicians.

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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Section 7 – 510(k) Summary

1. 510(k) Summary

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.

2. Date 510K Summary prepared: September 22, 2016

3. Administrative Information

Official Correspondent:	Dave Kim / Mtech Group 8310 Buffalo Speedway, Houston, TX 77025 Tel: +713-467-2607 Fax: +713-583-8988 Contact person: Mr. Dave Kim (davekim@mtech-inc.net)
510(k) Submitter:	VATECH Co., Ltd. Address: 13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449, Korea Tel: +82-31-379-9492 Fax: +82-31-379-9400 Contact person: Daniel Kim / Manager (daniel.kim@vatech.co.kr)

4. Device Information

Type of 510(k) Submission:	Traditional
Trade or Proprietary Name:	PaX-i3D Green Premium (Model: PCT-90LH)
Common or Usual Name:	Dental Computed Tomography X-ray System
Regulation Classification:	Computed tomography x-ray system (21 CFR 892.1750)
Product Code:	OAS
Class of Device:	Class II
Panel:	Radiology

5. Predicate Device Information

Manufacturer:	VATECH Co., Ltd.
Predicate device:	PaX-i3D Ortho (TON-95LH) / K132983
Common or Usual Name:	X-Ray, Tomography, Computed, Dental
Regulation Classification:	Computed tomography x-ray system (21 CFR 892.1750)
Product Code:	OAS
Class of Device:	Class II
Panel:	Radiology

※ This predicate has not been subject to a design-related recall.

6. Reference Device Information

Manufacturer:	VATECH Co., Ltd.
Reference device:	PaX-i3D Smart (PHT-30LFO) / K152106
Common or Usual Name:	X-Ray, Tomography, Computed, Dental
Regulation Classification:	Computed tomography x-ray system (21 CFR 892.1750)
Product Code:	OAS
Class of Device:	Class II
Panel:	Radiology

※ This predicate has not been subject to a design-related recall.

7. Device Description

PaX-i3D Green Premium (Model: PCT-90LH), a digital radiographic imaging system, acquires and processes multi FOV diagnostic images for a dentist and an ENT specialist. Specifically designed for dental and ENT radiography, PaX-i3D Green Premium (Model: PCT-90LH) is a complete digital X-ray system equipped with imaging viewers, X-ray generator and a dedicated SSXI detector.
The digital CBCT system is based on a CMOS digital X-ray detector. The CMOS CT detector is used to capture 3D radiographic images of head, neck and craniofacial anatomy for ENT, oral surgery, implant and orthodontic treatment. PaX-i3D Green Premium (Model: PCT-90LH) can also acquire 2D diagnostic image data in panoramic and cephalometric mode.

Key components of the device

1) PaX-i3D Green Premium (Model: PCT-90LH) digital x-ray equipment
2) SSXI detector: Xmaru3104CF

Item	Description
Model	Xmaru3104CF
Detector Type	CMOS photodiode array
Pixel Size	99 µm @ 2X2 binning : PANO 198 µm @ 4X4 binning : Dental CT, ENT CT, i-CEPH
Active Area	310.4 x 36.4 mm
Frame Rate	107 fps (2x2 Binning) : PANO 308 fps (4x4 Binning) : Dental CT, ENT CT, i-CEPH
Analogue-Digital Conversion	14 bits
Converter	CsI:Ti
Energy Range	60 ~ 120 kV
Readout Type	Charge amplifier array
Video Output	Optic

3) X-ray generator

- Option 1

Item			Description
High Voltage Generator	Model		DG-08C22S1
	Rated output power		1,200 W
	Type		Inverter
	Normal/Pulse	kV	60 ~ 120 kV

Item			Description
		mA	4 ~ 10 mA
	Cooling		Air (Optional fan cooling, ≥ 60 ℃)
	Total filtration		Min. 2.5 mm Al
	Added filtration		2.0 mm Al
X-ray Tube	Manufacturer		Superior
	Model		SXR-130-15-0.5 (Stationary Anode type)
	Focal spot size		0.5 mm
	Target Angle		15 degree
	Inherent Filtration		At least 1.1 mm Al equivalent at 80 kV
	Anode Heat Content		21 kJ
	Duty Cycle		1:20 or more (Exposure time : Interval time)

- Option 2

Item			Description
High Voltage Generator	Model		DG-08C22S2
	Rated output power		1,200 W
	Type		Inverter
	Normal/Pulse	kV	60 ~ 120 kV
		mA	4 ~ 10 mA
	Cooling		Air (Optional fan cooling, ≥ 60 ℃)
	Total filtration		Min. 2.5 mm Al
	Added filtration		2.0 mm Al
X-ray Tube	Manufacturer		C.E.I
	Model		OX/115-05 (Stationary Anode type)
	Focal spot size		0.5 mm
	Target Angle		15 degree
	Inherent Filtration		0.5mm Al
	Anode Heat Content		30 kJ
	Duty Cycle		1:60 or more (Exposure time : Interval time)

4) PC system

Item	Description
Operating System	Windows 8.1 Professional 64-Bit OS
CPU	Intel Xeon E5-1620v3 3.5GHz 2133 10MB cache CPU
RAM	32GB DDR4-2133 ECC RAM
HDD	1TB SATA 1st HDD
Graphics board	NVIDIA GEFORCE GTX980 Ti OC D5 6GB or greater
Ethernet interface	Broadcom 5761 Gigabit PCIe NIC
Serial Port (RS232)	HP Serial Port Adapter Kit
Power Supply	≥ 700 Watts (90% Efficiency)
Slots	1 PCI Express Gen3 x 8 Slot 2 PCI Express Gen3 x 16 slot 1 PCI Express Gen2 x 8 Slot 1 PCI Express Gen2 x 4 Slot

5) Imaging software

① EzDent-i: 2D viewer and patient management software

・Manufacturer: EWOO SOFT Co., Ltd.

- 510(k) Number: K150747
- Classification Number: 21CFR892.2050
- Product code: LLZ

② Ez3D-i: 3D image viewer

- Manufacturer: EWOO SOFT Co., Ltd.
- 510(k) Number: K150761
- Classification Number: 21CFR892.2050
- Product code: LLZ

8. Indication for use

PaX-i3D Green Premium (Model: PCT-90LH) is intended to produce panoramic, cephalometric or 3D digital x-ray images. It provides diagnostic details of the dento-maxillofacial, ENT, sinus and TMJ for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by healthcare professionals.

9. Comparison of Technological characteristics with the predicate device

	Subject Device	Predicate Device	Reference Device
Device Name	PaX-i3D Green Premium (Model: PCT-90LH)	PaX-i3D Ortho (TON-95LH)	PaX-i3D Smart (PHT-30LFO)
Applicant Name	VATECH Co., Ltd.	VATECH Co., Ltd.	VATECH Co., Ltd.
510(k) Number	N/A	K132983	K152106
Device Classification Name	X-Ray, Tomography, Computed, Dental	X-Ray, Tomography, Computed, Dental	X-Ray, Tomography, Computed, Dental
Classification Product Code	OAS	OAS	OAS
Regulation Number	21 CFR 892.1750	21 CFR 892.1750	21 CFR 892.1750
Indications for Use	PaX-i3D Green Premium (Model: PCT-90LH) is intended to produce panoramic, cephalometric or 3D digital x-ray images. It provides diagnostic details of the dento-maxillofacial, ENT, sinus and TMJ for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by healthcare professionals.	PaX-i3D Ortho (TON-95LH) is a computed tomography x-ray system intended to produce cross-sectional images of the oral anatomy by reconstructing a three dimensional radiographic images from the same axial plane taken at different angles. It provides diagnostic details of the maxillofacial areas for a dental treatment in adult and pediatric dentistry. The system also acquires carpal images for orthodontic treatment. The device is operated and used by physicians, dentists, and x-ray technicians.	PHT-30LFO is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and maxillofacial area for a precise treatment planning in adult and pediatric dentistry. The device is operated and used by physicians, dentists, and x-ray technicians.
Performance Specification	Panoramic, Cephalometric and computed tomography	Computed tomography	Panoramic, cephalometric and computed tomography
Input Voltage	AC 100 - 240 V	AC 100 - 240 V	AC 100 - 240 V
X-Ray source	(Option 1) SXR-130-15-0.5 (Option 2) OX/115-05	SXR-130-15-0.5	D-052SB
Tube Voltage	60 - 120 kV	50 - 120 kV	50 - 99 kV
Tube Current	4 - 10 mA	4 - 10 mA	4 - 16 mA
Focal Spot Size	0.5 mm	0.5 mm	0.5 mm
Exposure Time	Max. 18 s	Max. 24 s	Max. 18 s
Slice Width	Min. 0.1 mm	Min. 0.1 mm	Min. 0.1 mm
Total Filtration	(Option 1) Min. 2.5 mm Al	Min. 2.8 mm Al	2.8 mm Al

		(Option 2) Min. 2.5 mm Al		
Mechanical		Compact design	Compact design	Compact design
Electrical		LDCP logic circuit	LDCP logic circuit	LDCP logic circuit
Software		DICOM 3.0 Format compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible
2D Image Viewing Program		EzDent-i	EzDent-i	EasyDent
3D Image Viewing Program		Ez3D-i	Ez3D-i Ortho	Ez3D Plus
Anatomical Sites		Maxillofacial	Maxillofacial	Maxillofacial
Image Receptor	**Computed Tomography**	Xmaru3104CF	Xmaru2430CF Master Plus	Xmaru1404CF
	Panoramic		Reconstructed from 3D image data	
	Cephalometric		Reconstructed from 3D image data	Xmaru2301CF 1210SGA 910SGA Xmaru2301CF-O
Size of Imaging Volume		Max. 210 x 190 mm	Max. 240 x 210 mm	Xmaru1404CF: Max. 10 x 8.5 mm
Pixel Resolution	**Computed Tomography**	2.5 lp/mm -4x4 binning	5 lp/mm -2x2 binning 2.5 lp/mm -4x4 binning	Xmaru1404CF: - 5.0 lp/mm - 2x2 binning - 2.5 lp/mm - 4x4 binning
	Panoramic	5 lp/mm -2x2 binning	N/A	Xmaru1404CF: - 5.0 lp/mm - 2x2 binning - 2.5 lp/mm - 4x4 binning
	Cephalometric	2.5 lp/mm -4x4 binning	N/A	Xmaru2301CF: 5 lp/mm 1210SGA: 3.9 lp/mm 910SGA: 3.9 lp/mm Xmaru2301CF-O: 5 lp/mm
Pixel Size	**Computed Tomography**	198 ㎛ -4x4 binning	99 ㎛-2x2 binning 198 ㎛-4x4 binning	Xmaru1404CF: - 99 ㎛- 2x2 binning - 198 ㎛- 4x4 binning
	Panoramic	99 ㎛ -2X2 binning	N/A	Xmaru1404CF: - 99 ㎛- 2x2 binning - 198 ㎛- 4x4 binning
	Cephalometric	198 ㎛ -4x4 binning	N/A	Xmaru2301CF: 100 x 100 ㎛ 1210SGA: 127 x 127 ㎛ 910SGA: 127 x 127 ㎛ Xmaru2301CF-O: 100 x 100 ㎛

10. Performance Data

Summary of Performance Testing

The PaX-i3D Green Premium (Model: PCT-90LH) digital X-ray system described in this 510(k) is similar to the predicate device, PaX-i3D Ortho (TON-95LH) in terms of indications for use, materials, safety characteristics, and X-ray source.

Furthermore, the following information further substantiates the substantial equivalence between the subject device and predicate device:
The fundamental technological characteristics of the subject and predicate device are similar.
The sponsor tested the subject device in a laboratory and provided a non-clinical performance report. The same test protocol was used to test the predicated device for the purpose of comparing the performance between the predicate device. The sponsor certifies that adequate design and development controls (according to 21 CFR 820.30) were in place for manufacturing the subject device.

The differences are as follows.

- The subject device is equipped with Xmaru3104CF, a SSXI detector, which is used to capture PANO, i-CEPH, CT (Dental / ENT) images.
- The subject device utilizes iterative reconstruction algorithm, a CBCT imaging processing algorithm.
- In addition to the Dental CT mode, the subject device includes imaging modes; PANO, i-CEPH, ENT CT and 3D Photo.
- The subject device includes imaging viewer programs; EzDent-i (K150747) and Ez3D-i (K150761).

PaX-i3D Green Premium (Model: PCT-90LH), a digital radiographic imaging system is equipped with Xmaru3104CF, a SSXI detector, which is used to capture PANO, i-CEPH, Dental CT and ENT CT images. It has different active areas compared to Xmaru2430CF Master Plus of PaX-i3D Ortho (TON-95LH). Xmaru3104CF detector of the subject device offers different data output interface compared to the Xmaru2430CF Master Plus for PaX-i3D Ortho (TON-95LH). The added imaging modes of the subject device; PANO, i-CEPH and ENT CT require different radiograph exposure settings and field of view. However, the operating principles and indications for use of the radiograph imaging system remains similar as the predicate device. Both devices have the 3D photo mode which takes a 3D facial photograph of a patient and does not require X-ray exposure.

Non-clinical test was conducted for Xmaru3104CF of PaX-i3D Green Premium (Model: PCT-90LH). More specifically, the Modulation Transfer Function (MTF), Detective Quantum Efficiency (DQE) and Normalized Noise Power Spectrum (NNPS) performance were measured for Xmaru3104CF of the subject device and Xmaru2430CF Master Plus for the predicate device. (MTF and DQE results are objective performance evaluation parameters for a digital detector. MTF measures the resolution and expressed by the contrast difference in percentage. DQE represents the overall index for the detector's ability to converting incident X-ray into an image signal without much loss to the actual image object.) Based on the Non-Clinical Test results, the Xmaru3104CF detector has performed similarly or better than the predicate device, Xmaru2430CF Master Plus, in terms of the overall MTF and DQE performance.
The results of NNPS performance for Xmaru3104CF and Xmaru2430CF-Master Plus were similar. The change in the data output interface has not caused any changes in the performance or the level of artifacts. All performance parameters for both detectors have shown similar results.

The acceptance test was done according to the requirements of 21 CFR Part 1020.33 and IEC 61223-3-5, international performance standard for computed tomography X-ray system.

In addition, CT Image evaluation was performed on the finished X-ray equipment with the detector mounted. Contrast, Noise, CNR, and MTF, the representative indicators for 2D and 3D CT image quality were measured with iterative reconstruction algorithm. The results demonstrated that the general image quality of the subject device is equivalent or better than the predicate device.

The CBCT image reconstruction for PaX-i3D Green Premium (Model: PCT-90LH) applies iterative reconstruction algorithm for the reduction of noise in the CT image capture mode. Iterative reconstruction algorithm reconstructs raw data from the PaX-i3D Green Premium (Model: PCT-90LH) CBCT system to produce images containing noise levels less than or equal to images produced by standard filtered back projection reconstruction. The safety and effectiveness of iterative reconstruction algorithm have been demonstrated and confirmed by the previous 510k submission of the reference device, PaX-i3D Smart (PHT-30LFO) (K152106).

Clinical Data

The clinical considerations on the images in terms of quality and effectiveness sustained the diagnostic reliability and usefulness of images produced by the PaX-i3D Green Premium (Model: PCT-90LH) applications.

Software Verification and Validation Testing

Software verification and validation were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device 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.

PaX-i3D Green Premium (Model: PCT-90LH) utilizes imaging viewer programs; EzDent-i (K150747), Ez3D-i (K150761), both with FDA clearance.

Safety, EMC and Performance Data

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1(Ed. 3, 2005), IEC 60601-1-3 (Ed. 2, 2008), IEC 60601-2-63 (Ed. 1, 2012) were performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2.
The manufacturing facility is in conformance with the relevant EPRC standards as specified in 21 CFR 1020.30, 31, and 33 and the records are available for review.
PaX-i3D Green Premium (Model: PCT-90LH) conforms to the provisions of NEMA PS 3.1-3.18, Digital Imaging and Communications in Medicine (DICOM) Set.
Non-clinical consideration report according to FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" was provided.
Bench testing according to FDA Guidance "Format for Traditional and Abbreviated 510(k)s, section 18, Performance Testing – Bench" were performed.
Acceptance test and CT image evaluation report according to IEC 61223-3-4 and IEC 61223-3-5 were also performed.

All test results were satisfactory.

11. Conclusions

The subject device and the predicate device have similar indications for use and demonstrated similar technical characteristics. As demonstrated in the performance test, the Xmaru3104CF performed similar or better than the predicate device in various performance parameters such as DQE, MTF and NNPS. In addition, 2D and 3D CT

image evaluation of Contrast, Noise, CNR, and MTF further demonstrated the performance equivalency between the subject and predicate device. Quality assurance procedures are adhered to, and the specifications and functional requirements were met as the test results indicated.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, VATECH Co., Ltd. concludes that PaX-i3D Green Premium (Model: PCT-90LH) is substantially equivalent to the predicate device as described herein.