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

April 4, 2017

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

Re: K170731
Trade/Device Name: PaX-i Plus/PaX-i Insight (Model: PCH-30CS)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: March 8, 2017
Received: March 10, 2017

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)*
K170731

Device Name
PaX-i Plus/PaX-i Insight
(Model: PCH-30CS)

Indications for Use *(Describe)*

PCH-30CS is intended to produce panoramic or cephalometric digital x-ray images. It provides diagnostic details of the dento-maxillofacial, sinus and TMJ for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by physicians, dentists, 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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510(k) Summary

1. 510(k) Summary

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

2. Date 510K Summary prepared: March 28, 2017

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: Dongyub Lee / Manager (dongyub.lee@vatech.co.kr)

4. Device Information

Type of 510(k) Submission:	Traditional
Trade or Proprietary Name:	PaX-i Plus/PaX-i Insight (Model: PCH-30CS)
Common or Usual Name:	Digital X-ray Imaging System
Regulation Classification:	Extraoral Source X-ray System (21 CFR 872.1800)
Product Code:	MUH
Class of Device:	Class II
Panel:	Radiology

5. Predicate Device Information

Manufacturer:	VATECH Co., Ltd.
Predicate device:	PaX-i (PCH-2500) / K122155
Common or Usual Name:	Digital X-ray Imaging System
Regulation Classification:	Extraoral Source X-ray System (21 CFR 872.1800)
Product Code:	MUH
Class of Device:	Class II
Panel:	Radiology

6. Reference Device Information

Manufacturer:	VATECH Co., Ltd.
Predicate device:	Green Smart (Model: PHT-35LHS) / K162660
Common or Usual Name:	Digital X-ray Imaging System

Regulation Classification:	X-Ray, Tomography, Computed, Dental (21 CFR 892.1750)
Product Code:	OAS
Class of Device:	Class II
Panel:	Radiology

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

6. Device Description

PaX-i Plus / PaX-i Insight (Model: PCH-30CS) is an advanced 3-in-1 digital X-ray imaging system that incorporates PANO, CEPH (Optional) and 3D PHOTO (Optional) imaging capabilities into a single system and acquires 2D diagnostic image data in conventional panoramic and cephalometric modes.
The PaX-i Plus / PaX-i Insight dental systems are not intended for CBCT imaging

Key components of the device

1) PaX-i Plus / PaX-i Insight (Model: PCH-30CS) digital x-ray equipment
2) SSXI detector: Xmaru1501CF-PLUS, Xmaru1404CF-PLUS, Xmaru2602CF

Item	Description		
	PANO		CEPH
	PaX-i Plus	PaX-i Insight	PaX-i Plus / PaX-i Insight
Model	Xmaru1501CF-PLUS	Xmaru1404CF-PLUS	Xmaru2602CF
Detector Type	CMOS photodiode array	CMOS photodiode array	CMOS photodiode array
Pixel Size	100 µm	99 µm -2X2 binning (detector spec) 198 µm - 4X4 binning (system spec)	100 µm- Non binning (detector spec) 200 µm -2X2 binning (system spec)
Active Area	151.2 x 6.0 mm	135.8 x 36.4 mm	259 x 15.6 mm
Frame Rate	~287 fps (4x4 Binning)	~308 fps (4x4 Binning)	~330 fps (2x2 Binning)
Analogue-Digital Conversion	14 bits	14 bits	14 bits
Converter	CsI:Ti	CsI:Ti	CsI:Ti
Energy Range	50 ~ 120 kV	50 ~ 120 kV	50 ~ 120 kV
Readout Type	Charge amplifier array	Charge amplifier array	Charge amplifier array
Video Output	Optic	Optic	Optic

3) X-ray generator

Item			Description
High Voltage Generator	Model		DG-07D21T2
	Rated output power		1.0 kW
	Type		Inverter
	Normal/Pulse	kV	60 ~ 99 kV
		mA	4 ~ 10 mA
	Cooling		Air (Optional fan cooling, ≥ 60 ℃)
	Total filtration		Min. 2.5 mm Al
	Added filtration		1.5 mm Al (Fixed)
X-ray Tube	Manufacturer		Toshiba
	Model		D-052SB (Stationary Anode type)
	Focal spot size		0.5 x 0.5 mm
	Target Angle		5 degree
	Inherent Filtration		At least 0.8 mm Al equivalent at 50 kV
	Anode Heat Content		35 kJ
	Duty Cycle		1:60 or more (Exposure time : Interval time)

4) PC system

Item	Description

Item		Description
PaX-i Plus	Operating System	Window 10 Home 64-bit OS
	CPU	Intel Core i3-6100 3.7G 3M 2133 2C CPU
	RAM	4GB DDR4-2133 DIMM(1x4GB) RAM
	HDD	500GB 7200 RPM SATA 6G 3.5 HDD
	Graphics board	Integrated Graphic Card
	Ethernet interface	Intel Ethernet I210-T1 PCIe x1 Gb NIC
	Serial Port (RS232)	Integrated Motherboard
	Power Supply	≥ 280 Watts (90% efficient)
	Slots	1 full-height PCIe x16 (x4) 1 full-height PCIe x16 2 full-height PCIe x1
		1 PCI (optional)
PaX-i Insight	Operating System	Windows 10 Professional 64-Bit OS
	CPU	Intel Xeon E5-1607v3 3.1GHz 1866 4C
	RAM	16GB DDR4-2133 Registered RAM
	HDD	1TB SATA 1st HDD
	Graphics board	NVIDIA Geforce GTX970 D5 4GB
	Ethernet interface	Integrated Intel I218LM PCIeGbE
	Serial Port (RS232)	HP Serial Port Adapter kit
	Power Supply	≥ 700 Watts (90% efficient)
	Slots	2 PCI Express Gen3 x16 slot 1 PCI Express Gen3 x8 Slot 1 PCI Express Gen2 x4 Slot 1 PCI Express Gen2 x1 Slot
		1 PCI Slot

5) Imaging software

Item	Description
Image Viewing Program	EasyDent (Cleared under K122155)
	EzDent-i (K163533)

7. Indication for use

PCH-30CS is intended to produce panoramic or cephalometric digital x-ray images. It provides diagnostic details of the dento-maxillofacial, sinus and TMJ for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by physicians, dentists, and x-ray technicians.

8. Comparison of Technological characteristics with the predicate device

	Subject Device	Predicate Device	Reference Device
Device Name	PaX-i Plus / PaX-i Insight (Model: PCH-30CS)	PaX-i (Model: PCH-2500)	Green Smart (Model: PHT-35LHS)
Applicant Name	VATECH Co., Ltd.	VATECH Co., Ltd.	VATECH Co., Ltd.
510(k) Number	N/A	K122155	K162660
Device Classification Name	System, X-Ray, Extra oral Source, Digital	System, X-Ray, Extra oral Source, Digital	X-Ray, Tomography, Computed, Dental
Classification Product Code	MUH	MUH	OAS
Regulation Number	21 CFR 872.1800	21 CFR 872.1800	21 CFR 892.1750
Indications for Use	PCH-30CS is intended to produce panoramic or cephalometric digital x-ray images. It provides diagnostic details of the dento-maxillofacial, sinus and TMJ for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by physicians, dentists, and x-ray technicians.	PCH-2500 is a digital extra oral 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.	PHT-35LHS 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 dental treatments in adult and pediatric dentistry. The system also utilizes carpal images for orthodontic treatment. The device is operated and used by physicians, dentists and x-ray technicians.
Performance Specification	Panoramic, Cephalometric	Panoramic, Cephalometric	Panoramic, Cephalometric and computed tomography
Input Voltage	AC 100 - 240 V	AC 100 – 120 / 200-240 V	AC 100 - 240 V
X-Ray source	D-052SB	D-052SB	D-052SB
Tube Voltage	60 - 99 kV	60 - 90 kV	60 - 99 kV
Tube Current	4 - 10 mA	4 - 10 mA	4 - 16 mA
Focal Spot Size	0.5 x 0.5 mm	0.5 x 0.5 mm	0.5 x 0.5 mm
Scan Time	Max. 21 s	Max. 20.2 s	Max. 18 s
Slice Width	Min. 0.1 mm	Min. 0.1 mm	Min. 0.1 mm
Total Filtration	Min. 2.5 mm Al	2.8 mm Al	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
Image Viewing Program	EasyDent (Cleared under K122155)	EasyDent (Cleared under K122155)	EasyDent (Cleared under K162660)

		Subject Device		Predicate Device	Reference Device
		EzDent-i (K163533)			EzDent-i (K161117) Ez3D Plus (Cleared under K162660) Ez3D-i (K161246)
Anatomical Sites		Maxillofacial		Maxillofacial	Maxillofacial
Image Receptor	**PANO**	Xmaru1501CF-PLUS Xmaru1404CF-PLUS		Xmaru1501CF	(PANO/CBCT) Xmaru1404CF-PLUS
	CEPH	Xmaru2602CF		Xmaru2301CF	Xmaru2602CF
Pixel Resolution	**PANO**	Xmaru1501CF-PLUS	5 lp/mm	5 lp/mm	5 lp/mm -2x2 binning (detector spec) 2.5 lp/mm -4x4 binning (system spec)
		Xmaru1404CF-PLUS	5 lp/mm -2x2 binning (detector spec) 2.5 lp/mm -4x4 binning (system spec)		
	CEPH	5 lp/mm-Non binning (detector spec) 2.5 lp/mm -2x2 binning (system spec)		5 lp/mm	5 lp/mm-Non binning (detector spec) 2.5 lp/mm -2x2 binning (system spec)
Pixel Size	**PANO**	Xmaru1501CF-PLUS	100 µm	100 µm	99 µm -2X2 binning (detector spec) 198 µm - 4X4 binning (system spec)
		Xmaru1404CF-PLUS	99 µm -2X2 binning (detector spec) 198 µm - 4X4 binning (system spec)		
	CEPH	100 µm- Non binning (detector spec) 200 µm -2X2 binning (system spec)		100 µm	100 µm- Non binning (detector spec) 200 µm -2X2 binning (system spec)

※ The PaX-i Plus / PaX-i Insight dental systems are not intended for CBCT imaging.

9. Performance Data

Summary of Performance Testing

The PaX-i Plus/PaX-i Insight(Model: PCH-30CS) digital X-ray system described in this 510(k) is similar to the predicate device and reference device in terms of indications for use, materials, safety characteristics, and X-ray source.

The following information further substantiates the substantial equivalence between the subject device and predicate device:

a. The fundamental technological characteristics of the subject and predicate device are similar.
b. The imaging modes are similar; PANO and CEPH (Optional).
c. The same x-ray source
d. All viewing software programs have been cleared with previous 510k submissions; EasyDent (K122155)

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 performance of the subject and the predicate device for comparison. 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 between the subject device and the predicate device:

a. The subject device is equipped with new detectors, Xmaru1501CF-PLUS, Xmaru1404CF-PLUS and Xmaru2602CF.
b. In addition to modality, the subject device includes imaging modes; 3D PHOTO and Insight PAN(multi layer pano) mode for Panoramic
c. The subject device includes image viewing program; EzDent-i (K163533)
d. Electric Power Voltage
   - Subject device; AC 100-240 V
   - Predicate device; AC 100-120 V / 200 -240 V

Xmaru1404CF-PLUS and Xmaru2602CF have been cleared with previous 510k submissions; on reference device, PHT-35LHS(K162660).
The additional 3D PHOTO modality is also a function in reference device, PHT-35LHS(K162660).
In addition, Insight PAN modality, only available in EzDent-i (K163533) image viewing program, provides multi-layer panorama images with depth information, which a conventional single panorama image could not. Panorama images in Insight PAN mode demonstrate useful diagnostic information of a tooth, from anterior to posterior.

Based on Non-Clinical Test results of all detectors for the subject device, the CMOS panel of new detectors is exactly same to that of the predicate device. Therefore, the testing image patterns of the subject device show no aliasing phenomenon throughout the same spatial frequency as the predicate device.

The new detector Xmaru1501CF-PLUS is based on the predicate Xmaru1501CF and bench testing data in the non-clinical consideration shows similar or better performance.

For the new detector Xmaru1501CF-PLUS and Xmaru2602CF of the subject device, the Non-Clinical test results demonstrated better performance parameters compared to Xmaru1501CF and Xmaru2301CF, respectively, of the predicate device in terms of MTF, DQE and NPS. Furthermore, it results a superior signal-to-noise ratio than the predicate device in all spatial frequencies. The new CMOS panel in Xmaru1501CF-PLUS and Xmaru2602CF

generates better image quality. All performance parameters for Xmaru1501CF-PLUS and Xmaru2602CF detector have better results than Xmaru1501CF and Xmaru2301CF detector, respectively.

Based on Non-Clinical Test results of Xmaru1404CF-PLUS for the subject device, the CMOS panel of Xmaru1404CF-PLUS is higher performance than that of the predicate device(Xmaru1501CF). Pixel resolutions and pixel sizes in 2x2 binning mode for Xmaru1404CF-PLUS and Xmaru1501CF are similar. However, at all spatial frequency(0~5 lp/mm), the Xmaru1404CF-PLUS has much better signal-to-noise ratio performance than the predicative device.

The Xmaru1404CF-PLUS has higher DQE performance at all spatial frequencies. At low spatial frequency(~0.5 lp/mm), Xmaru1404CF-PLUS has a DQE of 2x2 binning: 57% / 4x4 binning: 56% and that of Xmaru1501CF is 59.7%. This result will be in a superior signal-to-noise ratio than Xmaru1501CF. Therefore, the image quality of Xmaru1404CF-PLUS is higher than Xmaru1501CF at same patient exposure.

The acceptance test was performed according to the requirements of 21 CFR Part 1020.30. and IEC 61223-3-4, international performance standard for dental x-ray equipment.
In addition, the dosimetric performance of the subject device and the predicate device was compared in terms of DAP. With the identical FDD(Focal Spot to Detector Distance), DAP measurement in the PANO mode of each device under the similar X-ray exposure conditions (exposure time, tube voltage, tube current) was the similar. In CEPH mode, the subject device has two image options, normal and fast, based on the exposure condition (exposure time, tube voltage, tube current) whereas the predicate device has no such option. The direct comparison of the dosimetric performance for each mode available in the subject and predicate device is difficult due to different exposure conditions such as the exposure time. DAP of the fast CEPH mode of the subject device was equivalent to the predicate device. Any user adjustment of the exposure setting in normal and fast mode of the subject device should consider the patient exposure level to be as low as possible.

Moreover, PANO / CEPH images from the subject and predicate devices are evaluated in the Clinical consideration and image quality evaluation report. The results demonstrated that the general image quality of the subject device is equivalent or better than the predicate device.

Clinical images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the device (note subject device detectors strongly based on predicate detectors) but they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended.

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.
A cybersecurity risk analysis was performed on the device software.

Satisfactory device testing result also indicates that the software part supports proper functioning of the subject device.

PaX-i Plus / PaX-i Insight (Model: PCH-30CS) provides the following image viewing programs;

- Image viewing program: EasyDent(K122155), EzDent-i(K163533)

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 the records are available for review.
PaX-i Plus / PaX-i Insight (Model: PCH-30CS) 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 image evaluation report according to IEC 61223-3-4 were also performed.

All test results were satisfactory.

10. Conclusions

The proposed device and the predicate device have similar indications for use and demonstrated similar technical characteristics. As demonstrated in the performance test, the Xmaru1501CF-PLUS, Xmaru1404CF-PLUS and Xmaru2602CF performed similar or better in comparison with the predicate device in various performance parameters such as DQE, MTF and NNPS. 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-i Plus / PaX-i Insight (Model: PCH-30CS) is substantially equivalent to the predicate device as described herein.