DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Vatech Co., Ltd.
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
Houston, Texas 77025

June 16, 2017

Re: K170066
Trade/Device Name: Green16/Green18 (Model: PHT-65LHS)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: December 1, 2016
Received: January 9, 2017

Dear Dave 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,

Michael D. O'Hara For

Robert A. 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)*

K170066

Device Name
Green16/Green18
(Model: PHT-65LHS)

Indications for Use *(Describe)*

PHT-65LHS 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.

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)

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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: May 15, 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: Daniel Kim / Manager (daniel.kim@vatech.co.kr)

4. Device Information

Type of 510(k) Submission:	Special
Trade or Proprietary Name:	Green16/Green18 (Model: PHT-65LHS)
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:	Green Smart (PHT-35LHS) / K162660
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.
No reference devices were used in this submission.

6. Device Description

Green16 / Green18 (Model: PHT-65LHS) is an advanced 5-in-1 digital X-ray imaging system that incorporates PANO, CEPH (Optional), CBCT, 3D MODEL Scan and 3D PHOTO (Optional) imaging capabilities into a single system.

PHT-65LHS, a digital radiographic imaging system, acquires and processes multi-FOV diagnostic images for dentists and ENT specialists. PHT-65LHS 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, oral surgery, implant and orthodontic treatment.

PHT-65LHS can also acquire 2D diagnostic image data in conventional panoramic and cephalometric modes.

Key components of the device

1) Green16/Green18 (Model: PHT-65LHS) digital x-ray equipment
2) SSXI detector: Xmaru1314CF, Xmaru1515CF, Xmaru2602CF

Item	Description		
	CBCT/PANO		CEPH
	Green16	Green18	Green16/Green18
Model	Xmaru1314CF	Xmaru1515CF	Xmaru2602CF
Detector Type	CMOS photodiode array	CMOS photodiode array	CMOS photodiode array
Pixel Size	99 µm -2X2 binning (detector spec) 198 µm - 4X4 binning (system spec)	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	CBCT-127.5 x 135.8 mm PANO-5.9 x 135.8 mm	CBCT-155.2 x 145.7 mm PANO-5.9 x 135.8 mm	15.6 x 259 mm
Frame Rate	~108 fps (4x4 Binning)	~95 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-07E22T2
	Rated output power		1.6 kW
	Type		Inverter
	Normal/Pulse	kV	60 ~ 99 kV
		mA	4 ~ 16 mA
	Cooling		Air (Optional fan cooling, ≥ 60 ℃)
	Total filtration		Min. 2.5 mm Al

Item		Description
	Added filtration	1.5 mm Al (Fixed) / PANO and CEPH mode 1.5 mm Al (Fixed) + 3.0 mm Al (Automatically added) / CBCT mode
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
Operating System	Windows 10 Professional 64-Bit OS
CPU	Intel i7-6700
RAM	16GB
HDD	500GB SATA 1st HDD
Graphics board	NVIDIA Geforce GTX1060 6GB or greater
Ethernet interface	10/100/1000 Mbps, RJ-45, 2 Port
Serial Port (RS232)	HP Serial Port Adapter kit
Power Supply	≥ 700 Watts (90% efficient)
Slots	1 PCI Express Gen3 x16 slot 1 PCI Express Gen2 x4 Slot 1 PCI Express Gen2 x1 Slot

5) Imaging software

Item	Description
2D Image Viewing Program	EasyDent (Cleared under K162660)
	EzDent-i (K161117)
3D Image Viewing Program	Ez3D Plus (Cleared under K162660)
	Ez3D-i (K161246)

7. Indication for use

Green16 / Green18 (Model: PHT-65LHS) 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.

8. Comparison of Technological characteristics with the predicate device

	Subject Device	Predicate Device
Device Name	Green 16 / Green 18 (Model: PHT-65LHS)	Green Smart (Model: PHT-35LHS)
Applicant Name	VATECH Co., Ltd.	VATECH Co., Ltd.
510(k) Number	N/A	K162660
Device Classification Name	X-Ray, Tomography, Computed, Dental	X-Ray, Tomography, Computed, Dental
Classification Product Code	OAS	OAS

		Subject Device		Predicate Device
Regulation Number		21 CFR 892.1750		21 CFR 892.1750
Indications for Use		PHT-65LHS 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.		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 and computed tomography		Panoramic, Cephalometric and computed tomography
Input Voltage		AC 100 - 240 V		AC 100 - 240 V
X-Ray source		D-052SB		D-052SB
Tube Voltage		60 - 99 kV		60 - 99 kV
Tube Current		4 - 16 mA		4 - 16 mA
Focal Spot Size		0.5 x 0.5 mm		0.5 x 0.5 mm
Scan Time		Max. 14.1 s		Max. 18 s
Slice Width		Min. 0.1 mm		Min. 0.1 mm
Total Filtration		Min. 2.5 mm Al		Min. 2.5 mm Al
Mechanical		Compact design		Compact design
Electrical		LDCP logic circuit		LDCP logic circuit
Software		DICOM 3.0 Format compatible		DICOM 3.0 Format compatible
2D Image Viewing Program		EasyDent (Cleared under K162660)		EasyDent (Cleared under K162660)
		EzDent-i (K161117)		EzDent-i (K161117)
3D Image Viewing Program		Ez3D Plus (Cleared under K162660)		Ez3D Plus (Cleared under K162660)
		Ez3D-i (K161246)		Ez3D-i (K161246)
Anatomical Sites		Maxillofacial		Maxillofacial
Image Receptor	**CT&PANO**	Xmaru1515CF		Xmaru1404CF-Plus
		Xmaru1314CF		
	CEPH	Xmaru2602CF		Xmaru2602CF
Size of Imaging Volume		Xmaru1515CF	Max. 180 x 100 mm	Max. 100 x 8.5 mm
		Xmaru1314CF	Max. 160 x 90 mm	
Pixel Resolution	**CT&PANO**	Xmaru1515CF	5 lp/mm -2x2 binning (detector spec) 2.5 lp/mm -4x4 binning (system spec)	5 lp/mm -2x2 binning (detector spec) 2.5 lp/mm -4x4 binning (system spec)
		Xmaru1314CF	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-Non binning (detector spec) 2.5 lp/mm -2x2 binning (system spec)

		Subject Device		Predicate Device
Pixel Size	CT&PANO	Xmaru1515CF	99 µm -2X2 binning (detector spec) 198 µm - 4X4 binning (system spec)	99 µm -2X2 binning (detector spec) 198 µm - 4X4 binning (system spec)
		Xmaru1314CF	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- Non binning (detector spec) 200 µm -2X2 binning (system spec)

9. Performance Data

Summary of Performance Testing

The Green 16/Green18(Model: PHT-65LHS) digital X-ray system described in this 510(k) is similar to the predicate 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:
The fundamental technological characteristics of the subject and predicate device are similar.
The imaging modes are similar; PANO, CEPH (Optional), CBCT, 3D MODEL Scan and 3D PHOTO (Optional)
All viewing software programs have been cleared with previous 510k submissions; EasyDent (K162660), Ez3D Plus (K162660), EzDent-i (K161117) and Ez3D-i (K161246).
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 CT image reconstruction algorithm (Iterative Recon) and MAR (Metal Artifact Reduction) algorithm are the same for the subject device and the predicate device.

The differences are as follows.

- The subject device is equipped with new detectors, Xmaru1314CF and Xmaru1515CF.
- The availability of diagnostics for ENT treatment

Green16/Green18 (Model: PHT-65LHS), a digital radiographic imaging system is equipped with Xmaru1314CF and Xmaru1515CF. Xmaru1314CF and Xmaru1515CF is a new SSXI detector, which is used to capture an image in panoramic, CBCT and Model Scan mode.

Based on Non-Clinical Test results of Xmaru1314CF and Xmaru1515CF for the subject device, the CMOS panel of Xmaru1314CF and Xmaru1515CF is exactly same to that of the Xmaru1404CF-Plus. Therefore, the testing image patterns of the new sensor show no aliasing phenomenon throughout the same spatial frequency as the predicate device.
All detectors are technically capable of 2x2 binning and 4x4 binning. In practice, both subject (PHT-65LHS) and predicate (PHT-35LHS) X-ray system capture images in 4x4 binning mode, which provides the same diagnostic image quality for the subject and predicate device.
Pixel resolutions and pixel sizes in 2x2 binning and 4x4 binning for subject device and predicate device detector are identical. Moreover, the Xmaru1314CF and Xmaru1515CF have performed similarly to the Xmaru1404CF-

Plus in terms of the Modulation Transfer Function (MTF), Detective Quantum Efficiency (DQE) and Normalized Noise Power Spectrum (NNPS). At a low spatial frequency (~0.5 lp/mm), both Xmaru1314CF an Xmaru1515CF have the same DQE of 49% (4x4binning) whereas Xmaru1404CF-Plus has 52% (4x4binning). The MTF and NNPS curves show that the Xmaru1314CF and Xmaru1515CF have similar resolution performance and image quality compared to Xmaru1404CF-Plus at all spatial frequencies. The performance parameters for all detectors have shown similar results.

The acceptance test was performed according to the requirements of 21 CFR Part 1020.30. 1020.33 and IEC 61223-3-5, international performance standard for computed tomography X-ray system. Contrast, Noise, CNR, and MTF, the representative indicators for CT image quality were measured with iterative reconstruction algorithm for the new X-ray equipment. The results demonstrated that the general image quality of the subject device is equivalent or better than the predicate device.

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), detector specifications, DAP measurement in the CEPH and PANO mode of each device under the same X-ray exposure conditions (exposure time, tube voltage, tube current) was the same.
In CBCT mode, 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 FOV 5x5 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/CBCT 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.

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.

Green 16/Green18(Model: PHT-65LHS) provides the following imaging viewer programs;

- 2D Image viewing program: EasyDent(K162660), EzDent-i(K161117)
- 3D Image viewing program: Ez3D Plus(K162660), Ez3D-i(K161246)

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.
Green 16/ Green18(Model: PHT-65LHS) 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.

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 Xmaru1314CF and Xmaru1515CF performed similar or better in comparison with the predicate device in various performance parameters such as DQE, MTF and NNPS. In addition, the 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 Green 16/Green18(Model: PHT-65LHS) is substantially equivalent to the predicate device as described herein.