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 20, 2016

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

Re: K162660
Trade/Device Name: Green Smart (Model PHT-35LHS)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: September 28, 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)*
K162660

Device Name
Green Smart (Model: PHT-35LHS)

Indications for Use *(Describe)*

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 a dental treatment 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.

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: 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:	Special
Trade or Proprietary Name:	Green Smart (Model: PHT-35LHS)
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 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.
No reference devices were used in this submission.

6. Device Description

Green Smart (PHT-35LHS) is an advanced 5 in 1 digital X-ray imaging system that incorporates PANO, CEPH (Optional), CBCT, MODEL Scan and 3D PHOTO (Optional) imaging capabilities into a single system.
Green Smart (PHT-35LHS), a digital radiographic imaging system, acquires and processes multi FOV diagnostic images for dentists. Specifically designed for dental radiography, Green Smart (PHT-35LHS) 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. With Auto Pano function, It also reconstructs the 3D CT data and produces 2D panoramic images without an additional X-ray scan.
Green Smart (PHT-35LHS) can also acquire 2D diagnostic image data in conventional panoramic and cephalometric imaging.

Key components of the device

1) Green Smart (Model: PHT-35LHS) digital x-ray equipment
2) SSXI detector: Xmaru1404CF-Plus, Xmaru2602CF

Item	Description	
	CBCT/PANO	**CEPHALOMETRIC**
Model	Xmaru1404CF-Plus	Xmaru2602CF
Detector Type	CMOS photodiode array	CMOS photodiode array
Pixel Size	198µm @ 4X4 binning	200 µm @ 2X2 binning
Active Area	CBCT-36.4 x 135.8 mm PANO-5.9 x 135.8 mm	15.6 x 36.4 mm
Frame Rate	~308 fps (4x4 Binning)	~330 fps (2x2 Binning)
Analogue-Digital Conversion	14 bits	14 bits
Converter	CsI:Ti	CsI:Ti
Energy Range	50 ~ 120 kV	50 ~ 120 kV
Readout Type	Charge amplifier array	Charge amplifier array
Video Output	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
	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

Item		Description
	Duty Cycle	1:60 or more (Exposure time : Interval time)

4) PC system

Item	Description
Operating System	Windows 8 Professional 64-Bit OS
CPU	Intel Xeon E5-1607v3 3.1GHz 1866 4C or faster
RAM	16GB DDR4-2133 Registered RAM
HDD	1TB SATA 1st HDD
Graphics board	NVIDIA Geforce GTX970 D5 4GB or greater
Ethernet interface	Integrated Intel I218LM PCIeGbE
Serial Port (RS232)	HP Serial Port Adapter Kit
Power Supply	≥ 700 Watts (90% Efficiency)
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
2D Image Viewing Program	EasyDent (Cleared under K152106)
	EzDent-i (K161117)
3D Image Viewing Program	Ez3D Plus (Cleared under K152106)
	Ez3D-i (K161246)

7. Indication for use

Green Smart (Model: 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.

8. Comparison of Technological characteristics with the predicate device

	Subject Device	Predicate Device
Device Name	Green Smart (Model: PHT-35LHS)	PaX-i3D Smart (Model: PHT-30LFO)
Applicant Name	VATECH Co., Ltd.	VATECH Co., Ltd.
510(k) Number	N/A	K152106
Device Classification Name	X-Ray, Tomography, Computed, Dental	X-Ray, Tomography, Computed, Dental
Classification Product Code	OAS	OAS
Regulation Number	21 CFR 892.1750	21 CFR 892.1750

		Subject Device	Predicate Device
Indications for Use		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.	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	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. 18 s	Max. 18 s
Slice Width		Min. 0.1 mm	Min. 0.1 mm
Total Filtration		Min. 2.5 mm Al	Min. 2.8 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 (Identical to K152106)	EasyDent
		EzDent-i (K161117)	
3D Image Viewing Program		Ez3D Plus (Identical to K152106)	Ez3D Plus
		Ez3D-i (K161246)	
Anatomical Sites		Maxillofacial	Maxillofacial
Image Receptor	**CT&PANO**	Xmaru1404CF-Plus	Xmaru1404CF
	CEPH	Xmaru2602CF	Xmaru2301CF
			1210SGA
			910SGA
			Xmaru2301CF-O
Size of Imaging Volume		Max. 100 x 8.5 mm	Max. 100 x 8.5 mm
Pixel Resolution	**CT&PANO**	2.5 lp/mm -4x4 binning	5 lp/mm -2x2 binning 2.5 lp/mm -4x4 binning
	CEPH	2.5 lp/mm -2x2 binning	5 lp/mm -Xmaru2301CF
			3.9 lp/mm -1210SGA
			3.9 lp/mm -910SGA
			5 lp/mm -Xmaru2301CF-O
Pixel Size	**CT&PANO**	198 µm @ 4X4 binning	99 µm -2X2 binning 198 µm -4x4 binning

		Subject Device	Predicate Device
	CEPH	200 µm -2X2 binning	100 µm -Xmaru2301CF
			127 µm -1210SGA
			127 µm -910SGA
			100 µm -Xmaru2301CF-O

9. Performance Data

Summary of Performance Testing

The Green Smart (Model: PHT-35LHS) 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 proposed device and predicate device:
The fundamental technological characteristics of the proposed and predicate device are similar.
All viewing software programs have been cleared with previous 510k submissions; EasyDent (K152106), Ez 3D Plus (K152106), 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 differences are as follows.

- The subject device is equipped with new detectors, Xmaru1404CF-Plus and Xmaru2602CF.
- The subject device includes additional imaging modes; 3D Photo and Model Scan
- The subject device includes imaging viewer programs; EzDent-i (K161117) and Ez3D-i (K161246).

Green Smart (Model: PHT-35LHS), a digital radiographic imaging system is equipped with Xmaru1404CF-Plus and Xmaru2602CF. Xmaru1404CF-Plus is a new SSXI detector, which is used to capture an image in panoramic, CBCT and Model Scan. mode Xmaru2602CF, a new scan type detector, obtains a cephalometric image.
In addition, the subject device is equipped with 3D photo mode and Model Scan mode. 3D photo mode does not require X-ray exposure. Model scan captures a dental model and reconstructs it in 3D.

Based on Non-Clinical Test results of Xmaru1404CF-Plus for the subject device, the CMOS panel of Xmaru1404CF-Plus is exactly same to that of the predicate device(Xmaru1404CF). Therefore, the testing image patterns of the new sensor show no aliasing phenomenon throughout the same spatial frequency as the predicate device. Moreover, the new sensor has performed similarly to the predicate device in terms of the DQE, MTF and NPS. All performance parameters for both detectors have shown similar results.

For the new detector Xmaru2602CF of the subject device, the Non-Clinical test results demonstrated better performance parameters compared to Xmary2301CF of the predicate device in terms of MTF, DQE and NPS. The new CMOS panel in Xmaru2602CF generates better image quality. All performance parameters for Xmaru2602CF detector have better results than Xmaru2301CF detector.

In addition, the acceptance test was performed according to the requirements of 21 CFR Part 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.

Software Verification and Validation Testing

Software verification and validation activities 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 Smart (Model: PHT-35LHS) provides the following imaging viewer programs;

- 2D Image viewing program: EasyDent (K152106), EzDent-i(K161117)
- 3D Image viewing program: Ez3D Plus (K152106), 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 Smart (Model: PHT-35LHS) 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.
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 Xmaru1404CF-Plus and Xmaru2602CF 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, it is the sponsor's opinion that Green Smart (Model: PHT-35LHS) is substantially equivalent to the predicate device as described herein.