Vatech Co., Ltd.
℅ Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7707 Fannin St. Ste 200
HOUSTON TX 77054

October 27, 2020

Re: K201627
Trade/Device Name: Green X (Model: PHT-75CHS)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: September 18, 2020
Received: September 24, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201627

Device Name
Green X
(Model: PHT-75CHS)

Indications for Use *(Describe)*

Green X (Model : PHT-75CHS) 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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Section 5 – 510(k) Summary
K201627

1. Traditional 510(k) Summary

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

2. Date 510K Summary prepared: October 22, 2020

3. Administrative Information

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Contact person: Mr. Dave Kim (davekim@mtech-inc.net)

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Contact person: Daniel Kim / Manager (daniel.kim@vatech.co.kr)

4. Device Information

Type of 510(k) Submission:	Traditional
Trade or Proprietary Name:	Green X(Model : PHT-75CHS)
Common or Usual Name:	System, X-ray, Computed tomography, Dental
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.
Trade or Proprietary Name:	Green16/Green18 (Model : PHT-65LHS)
Common or Usual Name:	System, X-ray, Computed tomography, Dental
Regulation Classification:	Computed tomography x-ray system(21 CFR 892.1750)
Product Code:	OAS
Class of Device:	Class II
Panel:	Radiology
510(k) Number:	K170066

6. Device Description

Green X (Model : PHT-75CHS) is an advanced 4-in-1 digital X-ray imaging system that incorporates PANO, CEPH(optional), CBCT and MODEL Scan imaging capabilities into a single system. Green X (Model : PHT-75CHS), a digital radiographic imaging system, acquires and processes multi-FOV diagnostic images for dentists. Designed explicitly for dental radiography. Green X is a complete digital X-ray system equipped with imaging viewers, an 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 the head, neck, oral surgery, implant and orthodontic treatment.

Green X (Model : PHT-75CHS) can also acquire 2D diagnostic image data in conventional PANO and CEPH modes.

7. Indication for use

Green X (Model : PHT-75CHS) 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. Substantial Equivalence Chart

	Subject Device	Predicate Device	Reference Device
Device Name	Green X (Model : PHT-75CHS)	Green16/Green18 (Model : PHT-65LHS)	PaX-i Plus / PaX-i Insight (Model : PCH-30CS)
Applicant Name	VATECH Co., Ltd.	VATECH Co., Ltd.	VATECH Co., Ltd.
510(k) Number	K201627	K170066	K170731
Device Classification Name	X-Ray, Tomography, Computed, Dental	X-Ray, Tomography, Computed, Dental	System, X-Ray, Extra oral Source, Digital
Classification Product Code	OAS	OAS	MUH
Regulation Number	21 CFR 892.1750	21 CFR 892.1750	21 CFR 872.1800
Indications for Use	Green X (Model : PHT-75CHS) 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-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.	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.
Performance Specification	Panoramic, Cephalometric and computed tomography	Panoramic, Cephalometric and computed tomography	Panoramic, Cephalometric
Input Voltage	AC 100 - 240 V	AC 100 - 240 V	AC 100 - 240 V
X-Ray source	D-052SB	D-052SB	D-052SB
Tube Voltage	60 - 99 kV	60 - 99 kV	60 - 99 kV
Tube Current	4 - 16 mA	4 - 16 mA	4 - 10 mA
Focal Spot Size	0.5 x 0.5 mm	0.5 x 0.5 mm	0.5 x 0.5 mm
Exposure Time	Max. 18.0 s	Max. 13.5 s	Max. 21 s
Slice Width	Min. 0.1 mm	Min. 0.1 mm	Min. 0.1 mm
Total Filtration	Min. 2.5 mm Al	Min. 2.5 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
2D Image Viewing Program	EzDent-i (K190087)	EzDent-i (K190087)	EasyDent(Cleared under K122155) EzDent-i (K190087)
3D Image Viewing Program	Ez3D-i (K200178)	Ez3D-i (K200178)	-

		Subject Device		Predicate Device		Reference Device	
						-	
Anatomical Sites		Maxillofacial		Maxillofacial		Maxillofacial	
Image Receptor	**CT&PANO**	Xmaru1314CF		Xmaru1515CF		Xmaru1501CF-Plus (PANO)	
				Xmaru1314CF		Xmaru1404CF-Plus (PANO)	
	CEPH	Xmaru2602CF		Xmaru2602CF		Xmaru2602CF	
Size of Imaging Volume		Xmaru1314CF	Max. 160 x 90 mm	Xmaru1515CF	Max. 180 x 100 mm	-	
				Xmaru1314CF	Max. 160 x 90 mm	-	
Pixel Resolution	**CT&PANO**	Xmaru1314CF	5 lp/mm -2x2 binning (detector spec) 2.5 lp/mm -4x4 binning (system spec)	Xmaru1515CF	5 lp/mm -2x2 binning (detector spec) 2.5 lp/mm -4x4 binning (system spec)	Xmaru1501CF-PLUS	5 lp/mm
				Xmaru1314CF	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-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)	
Pixel Size	**CT&PANO**	Xmaru1314CF	99 µm -2X2 binning (detector spec) 198 µm - 4X4 binning (system spec)	Xmaru1515CF	99 µm -2X2 binning (detector spec) 198 µm - 4X4 binning (system spec)	Xmaru1501CF-PLUS	100 µm
				Xmaru1314CF	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- 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 X (Model : PHT-75CHS) 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 the predicate device : The fundamental technological characteristics of the subject and predicate device are similar. The imaging modes are identical; PANO, CEPH (Optional), CBCT and 3D MODEL Scan. All viewing software programs have been cleared with previous 510k submissions; EzDent-i (K190087) and Ez3D-i (K200178). 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.

1) There are mainly three changes in hardware.

First, the subject device has applied a new Power Board(VT-PWR-014). It has been improved power stability compared to the Power Board(VT-PWR-010) used in the predicate device(K170066).

Second, the subject device's main MCU Board has been changed due to additional function(automation of chinrest and temple supports control).

Third, control buttons and LCD monitor in Control Panel have been replaced with LED touch panel in the subject device.

Safety tests for all of the changes mentioned above have been performed according to IEC 60601-1 standard. Other than the changes mentioned above, there are no changes to the main components(ex. X-ray tube, X-ray detector etc.).

2) Four Software functions have been added or improved

First, the subject device provides Endo mode which is suitable for Endodontic treatment. For the surgical endodontic procedures, it is necessary to have accurate information of the size and location of the periapical lesion and root apex in relation to structures. In order to achieve high resolution in Endo mode 1) the subject device's Endo mode constructs a high resolution voxel utilizing 99 µm pixel size, half of the 198 µm pixel size used in the predicate device's CBCT FOV. The quantitative evaluation has been performed for the verification and measured values for 4 parameters(Noise, Contrast, CNR, MTF 10%) have all satisfied IEC 61223-3-5 standard criteria. As a result of quantitative evaluation on spatial resolution, which is the main evaluation index of Endo mode, the MTF (@10%) value was measured to be 3.4 lp/mm . Furthermore, clinical images generated in Endo mode have been evaluated by a US licensed dentist and the results confirmed the sufficient diagnostic quality to provide accurate information of the size and location of the periapical lesion and root apex in relation to structure for endodontic surgical procedure.

Second, the Double Scan function of the subject device provides users with an image size equivalent to 16x15 FOV by vertically stitching two 16x9 FOV images. By stitching maxillary and mandible CT scan images, the Double Scan mode produces a large FOV image that is equivalent to FOV 16x15. The algorithm used for this stitching is the same as the general stitching algorithm.

The mechanical design of PHT-75CHS sets the overlapping area of the double scan to be 3cm to generate enough matching data to ensure successful image stitching. In order to quantitatively evaluate the degree of stitching match, quantitative evaluation was carried out through the average Structural Similarity Index (SSIM)

and Root-Mean-Square Error (RMSE); 0.9674 and 0.0027, respectively. In addition, the accuracy of the stitching match algorithm was verified with a low error rate of criteria less than 1voxel (0.3mm) through the RMSE for the distance registered. Clinical efficacy of the double scan function was further confirmed with 3D clinical consideration and evaluation without any sense of heterogeneity.

Third, Insight PAN 2.0 uses the same algorithm as Insight PAN, the predecessor, of the reference device, K170731. The difference is that the user can specify the diagnostic region of interest for Insight PAN 2.0 function. Insight PAN of the reference device(K170731) was to scan the entire maxillofacial area and provide 41 sectional slices of the area that the user specified. On the other hand, Insight PAN 2.0 in the subject device predefines a specific area to be diagnosed by the user before imaging in order to reduce patient dose. Accordingly, appropriate diagnose by imaging only interested area with low dose is possible. Image quality evaluation of the subject device has been performed and image quality factors(line pair resolution, low contrast resolution) satisfy IEC 61223-3-4 standard criteria. Having the same image quality factors as the reference device, the Insight PAN 2.0 allows the user to specify the X-ray exposure area before imaging to reduce the exposure dose as little as the limited area compared to reference device. Finally, clinical evaluation was performed to validate that the Insight PAN 2.0 function produces a depth defined dental anatomy with multiple layered diagnostic images and they are adequate for following challenging diagnostic cases:

a) diagnosis of individual root of multi-root
b) the bone around the impacted tooth (pericoronitis)
c) tooth deformity (dens in dente)
d) apical root shape

Fourth, both FDK(Back projection) and CS(iterative) algorithm are available in the subject device. Of the CT reconstruction algorithms, FDK(Back projection) and CS(Iterative) algorithms are widely used, and VATECH is also using FDK or CS algorithm in various predicate devices(K170066 - CS algorithm, K162660 – CS algorithm, K130432 – FDK algorithm, etc.). FDK algorithm maintains the average clinical image quality and has the advantage of faster image reconstruction time. CS algorithm has longer reconstruction time but has a better image quality compared to FDK algorithm. In accordance with the market needs, the subject device allows users to pre-select FDK or CS algorithm for CT image reconstruction. The quantitative evaluation has been performed for the verification and measured values for 4 parameters(Noise, Contrast, CNR, MTF 10%) of both FDK and CS reconstruction images have all satisfied IEC 61223-3-5 standard criteria.

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 FDK(back projection) and CS(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 dosimetry 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 dosimetry 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 12x9 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 device are evaluated in the CT 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 X (Model: PHT-75CHS) provides the following imaging viewer programs;

- 2D Image viewing program: EzDent-i(K190087)
- 3D Image viewing program: Ez3D-i(K200178)

- Safety, EMC and Performance Data

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1:2005+AMD1:2012(Edition 3.1), IEC 60601-1-3:2008+AMD1:2013 (Edition 2.1), IEC 60601-2-63:2012+AMD1:2017 (Edition 1.1) were performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2:2014 (Edition 4). 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 X 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

Safety and effectiveness of the hardware modifications and additional software functions have been clarified through each verification. Each software function has already been incorporated in previous devices which obtained premarket clearance by FDA and widely used in the market. Additional performance testing has been conducted for the subject device and all testing outcomes met the acceptance performance criteria according to the international standard and U.S. code, and proved to be equivalent to the predicate device.

The subject device and the predicate device have similar indications for use and demonstrated similar technical characteristics. As demonstrated in the performance test, 1) Endo mode was confirmed to be suitable for Endodontic treatment through clinical consideration and its was further confirmed that the performance standard was satisfied through CT image evaluation. 2) the registration process of double scan function and the accuracy of the algorithm were verified by matching with a low error rate of less than 1 voxel (0.3mm), the acceptance criteria, through the test results of RMSE for the distance . The clinical consideration further confirmed the clinical efficacy of the registration site. 3) The Insight PAN 2.0 function can limit the irradiation area under the same exposure conditions compared to the Insight PAN, the predecessor, thereby reducing the patient dose. 4) CS and FDK algorithm, previously cleared by FDA, can be elected in advance according to the

user needs in the subject device. Image quality evaluation of new software functions and algorithms were performed in compliance with IEC 61223-3-4 and IEC 61223-3-5. Both standard requirements were satisfied.
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 X(Model: PHT-75CHS) is substantially equivalent to the predicate device as described herein.