July 19, 2023

Vatech Co., Ltd
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7505 Fannin St. Ste 610
HOUSTON, TX 77054

Re: K231796
Trade/Device Name: Grreen X 12 (Model: PHT-75CHS)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: June 12, 2023
Received: June 20, 2023

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. 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231796

Device Name
Green X 12 (Model : PHT-75CHS)

Indications for Use *(Describe)*
Green X 12 (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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
K231796

1. Special 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: July 12, 2023

3. Administrative Information

Official Correspondent:	Dave Kim / Mtech Group Address: 7505 Fannin Street, Suite 610, Houston, TX 77054 Tel: +713-467-2607 Contact person: Mr. Dave Kim (davekim@mtechgroupllc.com)
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 X 12 (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:	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
510(k) Number:	K201627

6. Device Description

Green X 12 (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 12 (Model : PHT-75CHS), a digital radiographic imaging system, acquires and processes multi-FOV diagnostic images for dentists. Designed explicitly for dental radiography. Green X 12 (Model : PHT-75CHS) 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 12 (Model : PHT-75CHS) can also acquire 2D diagnostic image data in conventional PANO and CEPH modes.

The materials, safety characteristics, X-ray source, indications for use and image reconstruction/MAR(Metal Artifact Reduction) algorithm of the subject device are same to the predicate device (PHT-75CHS (K201627)). The difference from the predicate device is that the maximum FOV provided to the user is different by equipping the new CBCT/PANO detector. Also, New software functions (Auto Pano, Smart Focus, Scout) have been added.

7. Indication for use

Green X 12 (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 12 (Model : PHT-75CHS)	Green X (Model : PHT-75CHS)	Green Smart (Model : PHT-35LHS)
Applicant Name	VATECH Co., Ltd.	VATECH Co., Ltd.	VATECH Co., Ltd.
510(k) Number	K231796	K201627	K162660
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 872.1800
Indications for Use	Green X 12 (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.	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.	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.
Performance Specification	Panoramic, Cephalometric and computed tomography	Panoramic, Cephalometric and computed tomography	Panoramic, Cephalometric and computed tomography
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 - 16 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. 18.0 s	Max. 18.0 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 (K223820)	EzDent-i (K223820)	EasyDent(Cleared under K162660) EzDent-i (K223820)
3D Image Viewing Program	Ez3D-i (K222069)	Ez3D-i (K222069)	Ez3D Plus (Cleared under K162660)

		Subject Device		Predicate Device		Reference Device	
						Ez3D-i (K222069)	
Anatomical Sites		Maxillofacial		Maxillofacial		Maxillofacial	
Image Receptor	**CT&PANO**	Xmaru1404CF-PLUS		Xmaru1314CF		Xmaru1404CF-PLUS	
	CEPH	Xmaru2602CF		Xmaru2602CF		Xmaru2602CF	
Size of Imaging Volume		Xmaru1404CF-PLUS	Max. 120 x 85 mm	Xmaru1314CF	Max. 160 x 90 mm	Xmaru1404CF-PLUS	Max. 100 x 85 mm
Pixel Resolution	**CT&PANO**	Xmaru1404CF-PLUS	5 lp/mm -2x2 binning (system spec) 2.5 lp/mm -4x4 binning (system spec)	Xmaru1314CF	5 lp/mm -2x2 binning (system 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**	Xmaru1404CF-PLUS	99 µm -2X2 binning (system spec) 198 µm - 4X4 binning (system spec)	Xmaru1314CF	99 µm -2X2 binning (system 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 12 (Model : PHT-75CHS) digital X-ray system described in this 510(k) is identical to the predicate device in terms of indications for use, materials, safety characteristics, X-ray source and image reconstruction /MAR(Metal Artifact Reduction) process algorithm. The subject device is equipped with a new detector, Xmaru1404CF-PLUS.

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 identical. The imaging modes are similar; PANO, CEPH (Optional), CBCT and 3D MODEL Scan. All viewing software programs have been cleared with previous 510k submissions; EzDent-i (K223820) and Ez3D-i (K222069). 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.

For both devices, the differences are as follows.

1) The subject device is equipped with the Xmaru1404CF-PLUS detector which has been cleared with previous 510k submissions, PHT-35LHS (K162660).
2) The subject device includes additional Software functions; Auto Pano, Smart Focus, Scout
   a. The Auto Pano function reconstructs 3D CBCT data to create 2D panoramic images without separate X-ray scans. Auto Pano function was previously cleared by the reference device, PHT-35LHS (K162660).
   b. Smart focus function provides a high-resolution CBCT image in the FOV 40x40 mm that the user can designate from 1 to 3 images in the console SW after acquiring a projection of the entire tooth. Full arch CT (FOV 120x85 mm) and Auto Pano images are additionally provided as user options.
   c. Scout is a function provided in FOV 80x50 mm and Endo(40x40 mm) mode, which allows the user to preview and adjust the position of teeth before taking a Small FOV image.

The acceptance test was performed according to the requirements of 21 CFR Part 1020.30. 1020.33 and IEC 61223-3-5, Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance and constancy tests - Imaging performance of computed tomography X-ray equipment. 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 subject device performed equivalently to the predicate device in the general image quality.

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), exposure area, DAP measurement in the PANO mode of each device under the same X-ray exposure conditions (exposure time, tube voltage, tube current) was the same. The CEPH mode for the subject device and the predicate device also has the same FDD(Focal Spot to Detector Distance), the same detector specifications, the same DAP measurement under the same X-ray exposure conditions (exposure time, tube voltage, tube current).

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 area and exposure conditions(exposure time, tube voltage, tube current). Considering these differences, DAP was compared at the same FOV of 80x80 / 80x50 / Endo (40x40) mm supported by both devices. As a result of the comparison, the DAP of the Subjective device was lower than the Predicate device.

Moreover, the Clinical consideration and Image Quality Evaluation Report further demonstrated that the general image quality of the subject device is equivalent to the predicate device in PANO/CBCT mode.

- 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.

Cyber security was applied in compliance with FDA guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

Green X 12 (Model: PHT-75CHS) provides the following imaging viewer programs;

- 2D Image viewing program: EzDent-i (K223820)
- 3D Image viewing program: Ez3D-i (K222069)

- 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+AMD2:2021 (Edition 1.2) were performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2:2014+AMD1:2020 (Edition 4.1). 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. The Green X 12 conforms to the provisions of NEMA PS 3.1-3.18, Digital Imaging and Communications in Medicine (DICOM) Set.

Non-clinical consideration report was provided and cleared from previous 510k submissions(K162660) in accordance with the FDA guidelines "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices". Bench testing according to FDA Guidance "Format for Traditional and Abbreviated 510(k)s, Performance Testing – Bench" were performed. Image Quality evaluation report according to IEC 61223-3-4 and IEC 61223-3-5 were also performed.

We also reviewed the recommendations of FDA Pediatric Guidelines "Pediatric Information for X-ray Imaging Device Premarket Notifications" for safe imaging in the pediatric populations and included them in Instructions for use and labeling.

All test results were satisfactory.

10. Conclusions

Safety and effectiveness of New-detector application and additional software functions have been clarified through each verification. Subject device has been evaluated 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 same indications for use and demonstrated same technical characteristics. The new applied detector 'Xmaru1404CF-PLUS' was previously cleared by the reference device, PHT-35LHS (K162660). Among the added software functions; Auto Pano, Smart Focus and Scout modes, the Auto Pano function has already been incorporated in previous devices which obtained premarket clearance by FDA and widely used in the market. To demonstrate the performance of the Smart focus mode function, the FOV 40x40 mm image provided in Smart Focus mode was clinically evaluated by a US licensed dentist. And Image quality evaluation of new software functions was 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 have been verified.

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 12 (Model: PHT-75CHS) is substantially equivalent to the predicate device as described herein.