February 14, 2025

VATECH Co., Ltd
% Dave Kim
RA Consultant
Mtech Group LLC
7505 Fannin St. Suite 610
HOUSTON, TX 77054

Re: K243081
Trade/Device Name: Green X 21 (PHT-90CHO)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: January 14, 2025
Received: January 15, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Radiologic 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243081

Device Name

Green X 21 (PHT-90CHO)

Indications for Use *(Describe)*

Green X 21 (Model: PHT-90CHO) is intended to produce panoramic, cephalometric, or 3D digital X-ray images. It provides diagnostic details of the dento-maxillofacial, sinus, TMJ, and ENT 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.

510(k) Summary
K243081

1. 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: February 7, 2025

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:	Traditional
Trade or Proprietary Name:	Green X 21 (PHT-90CHO)
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

5. Predicate Device Information

Manufacturer:	VATECH Co., Ltd.
Trade or Proprietary Name:	Green X 18 (Model : PHT-75CHS)
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
510(k) Number:	K210329

6. Reference Device Information

Manufacturer:	VATECH Co., Ltd.
Trade or Proprietary Name:	Green X 12 (Model : PHT-75CHS)
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
510(k) Number:	K231796

7. Device Description

Green X 21 (Model : PHT-90CHO) is an advanced 6-in-1 digital X-ray system specifically designed for 2D and 3D dental radiography. This system features six imaging modalities: PANO, CEPH (optional), DENTAL CT, ENT CT, MODEL, and FACE SCAN, all integrated into a single unit.
Green X 21's imaging system is based on digital TFT detectors, accompanied by imaging viewers and an X-ray generator.
The materials, safety characteristics, X-ray source, indications for use and image reconstruction/MAR(Metal Artifact Reduction) algorithm of the subject device are same as the predicate device (PHT-75CHS (K210329)). The subject device differs from the predicate device in the following ways: It is equipped with new X-ray detectors for CT/PANO and CEPH modalities. This modification results in a different maximum FOV provided in a single scan for CT mode compared to the predicate device. For CEPH modality, the subject device utilizes a one- shot imaging capture method.
Additionally, the subject device includes new modalities such as ENT CT and FACE SCAN with a face scanner, along with new software functions, including Auto Pano, Smart Focus, and Scout.

8. Indications for use

Green X 21 (Model: PHT-90CHO) is intended to produce panoramic, cephalometric, or 3D digital X-ray images. It provides diagnostic details of the dento-maxillofacial, sinus, TMJ, and ENT for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by healthcare professionals.

9. Comparison of Technological characteristics with the predicate device

		Subject Device		Predicate Device	
Device Name		Green X 21 (Model : PHT-90CHO)		Green X 18 (Model : PHT-75CHS)	
Applicant Name		VATECH Co., Ltd.		VATECH Co., Ltd.	
510(k) Number		K243081		K210329	
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	
Indications for Use		Green X 21 (Model: PHT-90CHO) is intended to produce panoramic, cephalometric, or 3D digital X-ray images. It provides diagnostic details of the dento- maxillofacial, sinus, TMJ, and ENT 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 18 (Model: PHT-75CHS) is intended to produce panoramic, cephalometric, or 3D digital x-ray images. It provides diagnostic details of the dento- maxillofacial, sinus, TMJ, and ENT for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by healthcare professionals.	
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	
Exposure Time		Max. 18.0 s		Max. 18.0 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		EzDent-i (K241114)		EzDent-i (K241114)	
3D Image Viewing Program		Ez3D-i (K231757)		Ez3D-i (K231757)	
Anatomical Sites		Maxillofacial		Maxillofacial	
X-ray detector	**CT&PANO**	Jupi1012X		Xmaru1524CF Master Plus OP	
	CEPH	Venu1012VD		Xmaru2602CF	
Size of Imaging Volume		Jupi1012X	Max. 210 x 190 mm	Xmaru1524CF Master Plus OP	Max. 180 x 150 mm
X-ray detector Active		Jupi1012X	249.6 x 300.8 mm	Xmaru1524CF Master Plus OP	233.04 x 145.73 mm
		Venu1012VD	250 x 300 mm	Xmaru2602CF	259 x 15.60 mm

area			
Pixel Size	**CT&PANO**	100 µm (1x1 binning) 200 µm (2x2 binning)	99 µm -2X2 binning 198 µm - 4X4 binning
	CEPH	125 µm	100 µm -non binning 200 µm -2X2 binning

10. Performance Data

- **Summary of Performance Testing**

The Green X 21 (Model : PHT-90CHO) 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 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 modalities are similar; PANO, CEPH (Optional), CBCT (Dental/ENT CT) and MODEL. All viewing software programs have been cleared with previous 510k submissions; EzDent-i (K241114) and Ez3D-i (K231757).

The differences between the subject device and predicate device:

1) New X-ray detectors: CT/PANO (Jupi1012X) and CEPH(Venu1012VD)
2) New modalities: ENT CT and FACE SCAN
3) New Software Functions: Auto Pano, Smart Focus, and Scout mode

First difference, New X-ray detectors

The subject device is equipped with New X-ray detectors(CT/PANO modality; Jupi1012X and CEPH modality; Venu1012VD).

The subject device was tested and evaluated in a laboratory using the same test protocol as the predicate device to compare non-clinical and clinical performance. Non-clinical tests were conducted for the subject device's new X-ray detectors, comparing their performance with the predicate device in terms of Modulation Transfer Function (MTF), Detective Quantum Efficiency (DQE), and Noise to Power Spectrum (NPS).

According to the results of non-clinical tests, the pixel size of the new CT/PANO X-ray detector(Jupi1012X) was found to be very similar to that of the predicate device(Xmaru1524CF Master Plus OP). Consequently, the image test patterns of the Jupi1012X clearly demonstrate test objects across the same spatial frequency range as the Xmaru1524CF Master Plus OP without any aliasing artifacts. The Jupi1012X showed more stable or superior performance compared to the Xmaru1524CF Master Plus OP in terms of DQE, MTF, and NPS, with particularly better stability in high-frequency regions than in low-frequency regions. Additionally, based on the MTF 10% criterion, the Jupi1012X could distinguish up to 3.5 line pairs, while the Xmaru1524CF Master Plus OP could only distinguish up to 2.5 line pairs.

In CEPH modality, the pixel size of the new X-ray detector(Venu1012VD) was also similar to the 100 μm (non binning) pixel size supported by the predicate device's CEPH x-ray detector(Xmaru2602CF). The image test patterns obtained with the Venu1012VD also demonstrate test objects across the same spatial frequency range as the Xmaru2602CF without aliasing artifacts.
While the Venu1012VD exhibited superior performance in DQE, MTF, and NPS, the Xmaru2602CF demonstrated better performance in NPS due to its lower noise level. However, Venu1012VD's higher MTF values indicate its capability to deliver sharper images.

In conclusion, the diagnostic image quality of the new X-ray detectors was equivalent to or better than that of the predicate device, with no significant differences in efficiency and safety.

Second difference, New modalities

The subject device includes additional modalities: ENT CT and FACE SCAN.
The CT mode of the subject device is subdivided into DENTAL CT and ENT CT. The newly added ENT CT modality adheres to the same image quality standards as the Dental CT modality. It is specifically designed to limit radiation exposure to the ENT region (Facial Bone, Petrous Bone, Airway, Cochlear, Single Ear) for diagnostic purposes.
The FACE SCAN modality is an optional feature that overlays 3D photographs onto the patient's Dental CT images. This modality does not require X-ray exposure for its operation. Additionally, FACE SCAN is intended for aesthetic consultations, such as discussing facial appearance before and after procedures or orthodontic treatments, and is not designed for clinical diagnostic purposes.
The FACE SCAN feature is only available when the FOV is set to 210x190, 180x150, or 120x90 (mm).
The new functionality of the subject device meets the internally established criteria and has been designed to perform as intended.

Third difference, New Software functions

The new software functions (Auto Pano, Smart Focus, and Scout) are the same as those previously cleared in the reference device, Green X 12 (PHT-75CHS, K231796).
The Auto Pano function reconstructs 3D CBCT data to create 2D panoramic images without separate X-ray scans.
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 120x90 mm) and Auto Pano images are additionally provided as user options.
Scout is a function provided in FOV120x50, 80x50, 50x50 mm and Endo(40x40 mm) mode, which allows the user to preview and adjust the position of teeth before actual image acquisition.

The acceptance test was conducted in accordance with the requirements of 21 CFR Part 1020.30, 1020.31, 1020.33, 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), and IEC 61223-3-4 (Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray equipment).
The CT modality was evaluated through quantitative testing to verify and measure four key parameters representing CT image quality: noise, contrast, CNR, and MTF 10%. These evaluations

were conducted using the provided reconstruction algorithms, FDK(back projection) and CS(iterative). For PANO and CEPH modalities, quantitative assessments were performed with an emphasis on line pair resolution and low contrast performance using phantoms. The evaluation also included the newly added software functions, all of which met the standards specified in IEC 61223-3-4 and IEC 61223-3-5.

In addition, the dosimetric performance of the subject device and predicate device was compared in terms of DAP. For the PANO modality, although the X-ray detectors differ, both devices demonstrate the technical characteristics of having the same FDD (Focal Spot to Detector Distance) and exposure area.
When tested under the same exposure conditions (image option: High Resolution Mode), the DAP measurement results are similar.

For the CEPH modality, both devices have the same FDD (Focal spot to Detector Distance). However, the predicate device utilizes a scan-type X-ray detector, while the subject device employs a one-shot type X- ray detector. As a result, differences in X-ray detector specifications and exposure conditions make direct comparison under identical conditions difficult.
Although the exposure conditions for the two devices are not equivalent, a DAP evaluation was conducted using the default settings of image option (High Resolution Mode) with the same name to compare DAP values. The results indicate that the DAP of the subject device was more than twice that of the predicate device. However, the subject device utilizes a one-shot type, operating with approximately one-fourth the exposure time of the predicate device. This reduces motion artifacts during X-ray imaging and enhances patient convenience.

For the CT modality, while both devices have the same FDD (Focal Spot to Detector Distance), they differ in X-ray detector specifications. Consequently, their exposure conditions and image acquisition sequences are designed differently. The FOV provided by the two devices also differs, and the variations in exposure conditions make a direct comparison of DAP under identical conditions difficult. However, for
most comparable or equivalent FOVs, the results confirmed a slight increase in DAP for the subject device. Nonetheless, the maximum FOV provided by the subject device demonstrated a reduced radiation dose compared to the predicate device.

Additionally, PANO/CEPH/CT images from the subject and predicate device are evaluated in the Image Quality Evaluation Report and Clinical consideration. The results demonstrated that the subject device performed equivalently or better than the predicate device in overall image quality.

Software/Firmware Verification and Validation Testing

Software verification and validation were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions." The software for this device was considered as a "Basic Documentation Level", since a failure or latent flaw in the software would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures.

Green X 21 (Model: PHT-90CHO) provides the following imaging viewer programs;
2D Image viewing program: EzDent-i (K241114)
3D Image viewing program: Ez3D-i (K231757)

Safety and EMC and Performance Data

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601- 1:2005+AMD1:2012+AMD2:2020(Edition 3.2), IEC 60601-1-3:2008+AMD1:2013+AMD2:2021 (Edition 2.2),
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).

Bench Testing

Non-clinical consideration report was provided 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.

Applied FDA Guidance

"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submission" "Off-the-Shelf Software Use in Medical Devices"
"Pediatric Information for X-ray Imaging Device Premarket Notifications" All test results were satisfactory.

11. Conclusions

Comprehensive verification of the subject device has been performed and evaluated as the basis of a determination of substantial equivalence.
The subject device and the predicate device have the same indications for use and exhibit similar technical characteristics. The performance data for the subject device demonstrates equivalence or superiority to the predicate device in several aspects.
The newly applied X-ray detector has been proven in performance tests to perform equivalently or better compared to the predicate device across various performance parameters, including DQE, MTF, and NPS. Additionally, the image quality of the new X-ray detectors, including the newly added modality ENT CT, has been evaluated in compliance with IEC 61223-3-4 and IEC 61223-3-5. Both standard requirements were met. The FACE SCAN modality is not intended for clinical diagnosis but is designed to assist with patient consultations during treatment. This modality has been evaluated according to internal criteria and confirmed to fulfill its intended purpose.

Auto Pano, Smart Focus and Scout modes have already been incorporated in previous devices which obtained premarket clearance from FDA (K231796). It was confirmed that both standard requirements were met through evaluation according to IEC 61223-3-4 and IEC 61223-3-5.
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 21 (Model: PHT-90CHO) is substantially equivalent to the predicate device as described herein.