February 21, 2025

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

Re: K243088
Trade/Device Name: Green X 12 SE (PHT-40CHS)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: January 23, 2025
Received: January 23, 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 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243088

Device Name

Green X 12 SE (PHT-40CHS)

Indications for Use *(Describe)*

Green X 12 SE (Model : PHT-40CHS) is intended to produce panoramic, cephalometric, or 3D 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 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
K243088

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: February 20, 2025

3. Administrative Information

Official Correspondent:	Dave Kim / Mtech Group LLC 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 SE (PHT-40CHS)
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 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
510(k) Number:	K231796

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6. Device Description

Green X 12 SE (Model : PHT-40CHS) 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 SE (Model : PHT-40CHS), a digital radiographic imaging system, acquires and processes multi-FOV diagnostic images for dentists. Designed explicitly for dental radiography. Green X 12 SE (Model : PHT-40CHS) 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 SE (Model : PHT-40CHS) 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 as the predicate device (PHT-75CHS (K231796)). The difference from the predicate device is that Green X 12 SE (Model : PHT-40CHS) is equipped with a new ethernet type detector and some features are deleted (Double Scan).

7. Indication for use

Green X 12 SE (Model : PHT-40CHS) is intended to produce panoramic, cephalometric, or 3D 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 healthcare professionals.

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8. Comparison of Technological characteristics with the predicate device

		Subject Device		Predicate Device	
Device Name		Green X 12 SE (Model : PHT-40CHS)		Green X 12 (Model : PHT-75CHS)	
Applicant Name		VATECH Co., Ltd.		VATECH Co., Ltd.	
510(k) Number		-		K231796	
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 12 SE (Model : PHT-40CHS) is intended to produce panoramic, cephalometric, or 3D 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 healthcare professionals.		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.	
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. 16.9 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**	Xmaru1404CF-PLUS Eth		Xmaru1404CF-PLUS	
	CEPH	Xmaru2602CF Eth		Xmaru2602CF	
Size of Imaging Volume		Xmaru1404CF-PLUS Eth	Max. 120 x 85 mm	Xmaru1404CF-PLUS	Max. 120 x 85 mm
Pixel Size	**CT&PANO**	99 µm -2X2 binning (system spec) 198 µm - 4X4 binning (system spec)		99 µm -2X2 binning (system 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 X 12 SE (Model : PHT-40CHS) 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 applied the 'Eth' series, which changed the optical communication method of the X-ray detector 'Xmaru1404CF-Plus (Pano/CT) & Xmaru2606CF (Ceph)' used in the predicate device to the Ethernet communication method. In addition, the SW function was simplified compared to the preceding device.

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 also Identical; PANO, CEPH (Optional), CBCT and MODEL. All viewing software programs have been cleared with previous 510k submissions; EzDent-i (K241114) and Ez3D-i (K231757). 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 the two devices, the differences are as follows.

1) The subject device is equipped with the Xmaru1404CF-PLUS Eth and Xmaru2602CF Eth detector where predicate device is equipped with Xmaru1404CF-Plus and Xmaru2602CF detector.
   'Eth' means a model with an Ethernet communication port.
2) The subject device has Double Scan features deleted compared to the predicate device. For this, the chinrest up/down motor for using the double scan mode has been removed. (D.C. stepping motor)
3) The capacitive touch keypad of the Control Panel Part (handle frame) has been changed to a membrane switch.

For the IQ performance testing, 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 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) and exposure area, DAP measurement in the PANO, CEPH, and CBCT mode of each device under the same X-ray exposure conditions (exposure time, tube voltage, tube current) was the same. The result images of the subject and predicate device in the Clinical Consideration Report and Image Quality Evaluation Report (Model: PHT-40CHS) were considered as well to ensure the validity of the dose evaluation.

Moreover, the Non-clinical considerations and Image Quality Evaluation Report further demonstrated that the general image quality of the subject device is equivalent to the predicate device.

- **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 | FDA." The software for this device was considered was considered as a basic documentation, 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 12 SE (Model: PHT-40CHS) 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). 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 SE 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 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"
  - "Content of Premarket Submissions for Device Software Functions | FDA"
  - "Off-the-Shelf Software Use in Medical Devices"
  - "Pediatric Information for X-ray Imaging Device Premarket Notifications"
  - "Electromagnetic Compatibility (EMC) of Medical Devices"

All test results were satisfactory.

10. Conclusions

Safety and effectiveness of new-detector application 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 is designed as a lower-end product line that provides imaging performance equivalent to that of the predicate device. In this regard, some hardware has been removed/changed (d.c. stepping motor, membrane switch), and the data transmission method has been changed from optical communication to Ethernet communication. The subject device and the predicate device have same indications for use and demonstrated same technical characteristics. 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 12 SE (Model: PHT-40CHS) is substantially equivalent to the predicate device as described herein.