March 31, 2026

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

Re: K260093
Trade/Device Name: Green X 12 VE (PHT-70CHS); Green X VE (PHT-70CHS)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: March 3, 2026
Received: March 4, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

for

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.

510(k) Number *(if known)*
K260093

Device Name
Green X 12 VE (Model: PHT-70CHS)
Green X VE (Model: PHT-70CHS)

Indications for Use *(Describe)*
PHT-70CHS 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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K260093 510(k) Summary

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: Dec. 19, 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
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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 VE (Model: PHT-70CHS) Green X VE (Model: PHT-70CHS)
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

5-1. Predicate Device for Green X 12 VE

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

5-2. Predicate Device for Green X VE

Manufacturer:	VATECH Co., Ltd.
Trade or Proprietary Name:	Green X 21 (Model : PHT-90CHO)
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:	K243081

6. Device Description

The PHT-70CHS is a 4-in-1 digital X-ray system designed for both 2D and 3D dental radiographic imaging. The system integrates panoramic imaging, optional cephalometric imaging, dental computed tomography, and model imaging functions into a single unit. It is intended for dental diagnostic purposes and is capable of acquiring and processing multi-field-of-view digital radiographic images.
The PHT-70CHS is a complete digital radiographic imaging system that includes an X-ray generator, dedicated image receptors, and compatible image viewing software. The system supports acquisition of both 2D diagnostic images, including panoramic and cephalometric images, and 3D diagnostic images using cone beam computed tomography.
The materials, safety characteristics, X-ray source, indications for use, and image reconstruction including metal artifact reduction algorithms of the subject device are the same as those of the predicate devices PHT-75CHS (K231796) and PHT-90CHO (K243081).
Green X 12 VE and Green X VE are differentiated by the configuration of the CT and panoramic image receptors, which is reflected in their respective trade naming. Green X 12 VE is equipped with the Xmaru1404CF-PLUS Eth detector, while Green X VE is equipped with the Jupi0606X1 detector. Both configurations utilize the Xmaru2602CF Eth detector for cephalometric imaging.

7. Indication for use

PHT-70CHS 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.

8. Substantial Equivalence Chart

8-1. Green X 12 VE - Substantial Equivalence Chart

		Subject Device		Predicate Device		Comparison
Device Name		Green X 12 VE (Model : PHT-70CHS)		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		Same
Classification Product Code		OAS		OAS		Same
Regulation Number		21 CFR 892.1750		21 CFR 892.1750		Same
Indications for Use		Green X 12 VE (Model: PHT-70CHS) 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.		Similar
Performance Specification		Panoramic, Cephalometric and computed tomography		Panoramic, Cephalometric and computed tomography		Same
Input Voltage		AC 100 - 240 V		AC 100 - 240 V		Same
X-Ray source		D-052SB		D-052SB		Same
Tube Voltage		60 - 99 kV		60 - 99 kV		Same
Tube Current		4 - 16 mA		4 - 16 mA		Same
Focal Spot Size		0.5 x 0.5 mm		0.5 x 0.5 mm		Same
Exposure Time		Max. 16.9 s		Max. 16.9 s		Same
Slice Width		Min. 0.1 mm		Min. 0.1 mm		Same
Total Filtration		Min. 2.5 mm Al		Min. 2.5 mm Al		Same
Mechanical		Compact design		Compact design		Same
Electrical		LDCP logic circuit		LDCP logic circuit		Same
Software		DICOM 3.0 Format compatible		DICOM 3.0 Format compatible		Same
2D Image Viewing Program		EzDent-i (K241114)		EzDent-i (K223820)		Similar
3D Image Viewing Program		Ez3D-i (K231757)		Ez3D-i (K222069)		Similar
Anatomical Sites		Maxillofacial		Maxillofacial		Same
Image Receptor	**CT&PANO**	Xmaru1404CF-PLUS Eth		Xmaru1404CF-PLUS		Comparable 1)
	CEPH	Xmaru2602CF Eth		Xmaru2602CF		Comparable 2)
Size of Imaging Volume		Xmaru1404CF-PLUS Eth	Max. 120 x 85 mm	Xmaru1404CF-PLUS	Max. 120 x 85 mm	Same
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)		Same
	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)		Same

Difference Summary:

The Green X 12 VE (Model: PHT-70CHS) dental computed tomography X-ray system described in this 510(k) is identical to the predicate device, Green X 12 (Model: PHT-75CHS), with respect to intended use, materials, safety characteristics, X-ray source, image reconstruction, and MAR (Metal Artifact Reduction) algorithms.
The following two things have changed:

1) The communication method of the X-ray detector has been changed.
   Comparable 1)
   The Xmaru1404CF-PLUS Eth maintains the same sensor structure, imaging performance, and clinical functionality as the existing Xmaru1404CF-PLUS, with the communication method between the detector and the system changed from optical communication to Ethernet communication.
   Comparable 2)
   The Xmaru2602CF Eth maintains the same sensor structure, imaging performance, and clinical functionality as the existing Xmaru2602CF, with the communication method between the detector and the system changed from optical communication to Ethernet communication.

The above Xmaru1404CF-PLUS Eth and Xmaru2602CF Eth detectors have already been cleared under 510(k) K243088, and this change does not affect the safety or performance of the device.

2) The latest version of the 2D/3D image viewing software (3rd party software) has been applied.
   - Predicate Device: EzDent-i (K223820), version 3.4 / Ez3D-i (K222069), version 5.4
   - Subject Device: EzDent-i (K241114), version 3.5 / Ez3D-i (K231757), version 5.5

The 3rd party software does not directly affect the safety or performance of the Subject Device. In addition, the scope of functions available for use with the Subject Device remains within the FDA 510(k)-cleared indications and functionality of EzDent-i and Ez3D-i, respectively.

8-2. Green X VE - Substantial Equivalence Chart

		Subject Device		Predicate Device		Comparison
Device Name		Green X VE (Model : PHT-70CHS)		Green X 21 (Model : PHT-90CHO)		-
Applicant Name		VATECH Co., Ltd.		VATECH Co., Ltd.		-
510(k) Number		-		K243081		-
Device Classification Name		X-Ray, Tomography, Computed, Dental		X-Ray, Tomography, Computed, Dental		Same
Classification Product Code		OAS		OAS		Same
Regulation Number		21 CFR 892.1750		21 CFR 892.1750		Same
Indications for Use		Green X VE (Model PHT-70CHS) 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 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.		Similar
Performance Specification		Panoramic, Cephalometric and computed tomography		Panoramic, Cephalometric and computed tomography		Same
Input Voltage		AC 100 - 240 V		AC 100 - 240 V		Same
X-Ray source		D-052SB		D-052SB		Same
Tube Voltage		60 - 99 kV		60 - 99 kV		Same
Tube Current		4 - 16 mA		4 - 16 mA		Same
Focal Spot Size		0.5 x 0.5 mm		0.5 x 0.5 mm		Same
Exposure Time		Max. 18.0 s		Max. 18.0 s		Same
Slice Width		Min. 0.1 mm		Min. 0.1 mm		Same
Total Filtration		Min. 2.5 mm Al		Min. 2.5 mm Al		Same
Mechanical		Compact design		Compact design		Same
Electrical		LDCP logic circuit		LDCP logic circuit		Same
Software		DICOM 3.0 Format compatible		DICOM 3.0 Format compatible		Same
2D Image Viewing Program		EzDent-i (K241114)		EzDent-i (K241114)		Same
3D Image Viewing Program		Ez3D-i (K231757)		Ez3D-i (K231757)		Same
Anatomical Sites		Maxillofacial		Maxillofacial		Same
Image Receptor	**CT&PANO**	Jupi0606X1		Jupi1012X		Comparable 3)
	CEPH	Xmaru2602CF Eth		Venu1012VD		Comparable 4)
Size of Imaging Volume		Jupi0606X1	Max. 180 x 100 mm	Jupi1012X	Max. 210 x 190 mm	Different - Comparable 3)
Pixel Size	**CT&PANO**	100 µm (1x1 binning) 200 µm (2x2 binning)		100 µm (1x1 binning) 200 µm (2x2 binning)		Same
	CEPH	200 µm (2x2 binning)		125 µm		Different - Comparable 4)

Difference Summary:
The Green X VE (Model: PHT-70CHS) dental CT X-ray system described in this 510(k) is identical to the predicate device, Green X 21 (Model: PHT-90CHO), with respect to intended use, materials, safety characteristics, X-ray source, image reconstruction, and MAR (Metal Artifact Reduction) algorithms.
However, differences exist in the image receptor configuration, resulting in variations in the image acquisition method and maximum field of view (FOV). In addition, there are differences in the versions of the 2D/3D image viewing software. These differences are described below.

Comparable 3)
There is a difference in the maximum available field of view (FOV) due to differences in the CT/PANO image detectors. The subject device is equipped with the Jupi0606X1 detector, providing a maximum FOV of 180 × 100 mm, whereas the predicate device is equipped with the Jupi1012X detector, providing a maximum FOV of 210 × 190 mm.
This difference is attributable to the physical size of the detectors and does not affect the fundamental imaging acquisition principles or the intended diagnostic purpose of the system.
Comparable 4)
As specifications of Green X VE CEPH mode is identical with that of Green X 12 VE, it is compared with Green X 12. Xmaru2602CF Eth maintains the same sensor structure, imaging performance, and clinical functionality as the existing Xmaru2602CF, with the communication method between the detector and the system changed from optical communication to Ethernet communication.

These differences are attributable to variations in detector configuration and physical specifications and do not adversely affect the safety or performance of the subject device. Also, Xmaru2602CF Eth detector has already been cleared under 510(k) K243088. Accordingly, the fundamental technological characteristics of the subject device are substantially equivalent to those of the predicate device.

Additionally, the latest version of the 2D/3D image viewing software (3rd party software) has been applied.
- Predicate Device: EzDent-i (K223820), version 3.4 / Ez3D-i (K222069), version 5.4
- Subject Device: EzDent-i (K241114), version 3.5 / Ez3D-i (K231757), version 5.5

The 3rd party software does not directly affect the safety or performance of the Subject Device. In addition, the scope of functions available for use with the Subject Device remains within the FDA 510(k)-cleared indications and functionality of EzDent-i and Ez3D-i, respectively.

9. Performance Data

- Summary of Performance Testing

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 equivalent; 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 subject device and predicate device, the differences are as follows.

1) The subject device is equipped with the Xmaru1404CF-PLUS Eth detector (Green X 12 VE) for CT/PANO mode and Xmaru2602CF Eth (Green X 12 VE, Green X VE) detector for CEPH mode whereas predicate device (Green X 12) is equipped with Xmaru1404CF-Plus and Xmaru2602CF detector. 'Eth' means a model with an Ethernet communication port.
2) The subject device (Green X VE) is equipped with the Jupi0606X1 detector for CT/PANO mode, providing a maximum field of view (FOV) of 180 mm × 100 mm, whereas the predicate device (Green X 21) is equipped with the Jupi1012X detector, providing a larger maximum FOV of 210 mm × 190 mm.

New X-ray detectors

The subject device is equipped with New X-ray detectors as follows.
Green X 12 VE: Xmaru1404CF-PLUS Eth for CT/PANO mode and Xmaru2602CF Eth for CEPH mode
Green X VE: Jupi0606X1 for CT/PANO mode and Xmaru2602CF Eth for CEPH mode
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), Noise Equivalent Dose (NED), and Noise to Power Spectrum (NPS).
For CT/PANO/CEPH detector of Green X 12 VE and CEPH detector of Green X VE, according to the results of non-clinical tests, the pixel size of the new detector(Xmaru1404CF-PLUS Eth / Xmaru2602CF Eth) was found to be equal to that of the predicate device(Xmaru1404CF-PLUS / Xmaru2602CF). Technically, there are no differences between the detectors besides communication methods. Consequently, the image test patterns of Xmaru1404CF-PLUS Eth clearly demonstrate test objects across the same spatial frequency range as Xmaru1404CF-PLUS without any aliasing artifacts. Both Xmaru1404CF-PLUS Eth and Xmaru2602CF Eth showed equivalent performance compared to Xmaru1404CF-PLUS and Xmaru2602CF in terms of DQE, MTF, and NPS.
For CT/PANO detector of Green X VE, according to the results of non-clinical tests, the pixel size of the new detector(Jupi0606X1) was found to be very similar to that of the predicate device(Jupi1012X). Consequently, the image test patterns of the Jupi0606X1 clearly demonstrate test objects across the same spatial frequency range as the Jupi1012X without any aliasing artifacts. Jupi0606X1 showed similar or better performance compared to Jupi1012X in terms of DQE, MTF, and NED.
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.

The acceptance test was conducted in accordance with the requirements of 21 CFR Part 1020.30, 1020.31, 1020.33, IEC 61223-3-7:2021 (Evaluation and routine testing in medical imaging departments - Part 3- 7: Acceptance and constancy tests - Imaging performance of X-ray equipment for dental cone beam computed tomography), and IEC 61223-3-4:2000 (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 software function additions, all of which met the requirements specified in IEC 61223-3-4:2000 and IEC 61223-3-7:2021.
In addition, the dosimetric performance of the subject device and the predicate device was compared in X-ray Dose Performance Comparison Evaluation Report, in terms of DAP.
For Green X 12 VE, With the identical FDD (Focal Spot to Detector Distance), exposure area, and exposure conditions, DAP measurement in the PANO, CEPH, and CBCT mode of each device was found to be equivalent.
For Green X VE, PANO and CEPH mode share identical FDD (Focal Spot to Detector Distance), exposure area, and exposure conditions with its predicate devices (Green X 21 for PANO and Green X 12 for CEPH) and DAP measurement of each device was found to be equivalent. There are some differences in FOVs and exposure conditions for CBCT mode between the two devices but applying similar exposure areas and irradiation conditions (tube voltage, tube current), the subjective device showed similar DAP measurements compared to its predicate device.

Moreover, the clinical considerations and Image Quality Evaluation Report further 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, "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 12 VE (Model: PHT-70CHS) and Green X VE (Model: PHT-70CHS) provides the following imaging viewer programs;
2D Image viewing program: EzDent-i (K241114)
3D Image viewing program: Ez3D-i (K231757)

- **Safety, 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. PHT-70CHS conforms to the provisions of NEMA PS 3.1-3.18, Digital Imaging and Communications in Medicine (DICOM) Set.

- 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 61223-3-4:2000 and IEC 61223-3-7:2021 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.

10. Conclusions

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, NPS, and NED. Additionally, the image quality of the new X-ray detectors has been evaluated in compliance with IEC 61223-3-4:2000 and IEC 61223-3-7:2021. Both standard requirements were met.
Safety and effectiveness of new-detector application have been clarified through each verification. Despite the differences in detector models, it was found that total dose level and image quality of subjective device is equivalent to the predicate device when similar exposure areas and exposure conditions are applied. Subject device has been evaluated according to the international standard and U.S. code and proved to be equivalent to the predicate device.
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 VE (Model: PHT-70CHS) and Green X VE (Model: PHT-70CHS) are substantially equivalent to the predicate device as described herein.