Vatech Co., Ltd
% Mr. Dave Kim
Contact Title Medical Device Regulatory Affairs
Mtech Group
7707 Fannin St., Ste. 200-Vlll
HOUSTON TX 77054

February 18, 2021

Re: K210329
Trade/Device Name: Green X 18(Model: PHT-75CHS)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: February 1, 2021
Received: February 4, 2021

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210329

Device Name

Green X 18 (Model : PHT-75CHS)

Indications for Use *(Describe)*

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, 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
K210329

1. Traditional 510(k) Summary

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

2. Date 510K Summary prepared: February 15, 2021

3. Administrative Information

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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 18 (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 18 (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 18 (Model : PHT-75CHS), a digital radiographic imaging system, acquires and processes multi-FOV diagnostic images for dentists. Designed explicitly for dental radiography. Green X 18 (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.
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 it is equipped with a new CBCT/PANO detector to provide users with a larger CBCT FOV.

7. Indication for use

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, 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	
Device Name		Green X 18 (Model : PHT-75CHS)		Green X (Model : PHT-75CHS)	
Applicant Name		VATECH Co., Ltd.		VATECH Co., Ltd.	
510(k) Number		K210329		K201627	
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 18 (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.	
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 (K202116)		EzDent-i (K202116)	
3D Image Viewing Program		Ez3D-i (K200178)		Ez3D-i (K200178)	
Anatomical Sites		Maxillofacial		Maxillofacial	
Image Receptor	**CT&PANO**	Xmaru1524CF Master Plus OP		Xmaru1314CF	
	CEPH	Xmaru2602CF		Xmaru2602CF	
Size of Imaging Volume		Xmaru1524CF Master Plus OP	Max. 180 x 150 mm	Xmaru1314CF	Max. 160 x 90 mm
Pixel Resolution	**CT&PANO**	Xmaru1524CF Master Plus OP	5 lp/mm -2x2 binning 2.5 lp/mm -4x4 binning	Xmaru1314CF	5 lp/mm -2x2 binning 2.5 lp/mm -4x4 binning
	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)	
Pixel Size	**CT&PANO**	Xmaru1524CF Master Plus OP	99 µm -2X2 binning 198 µm - 4X4 binning	Xmaru1314CF	99 µm -2X2 binning 198 µm - 4X4 binning
	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 18 (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, Xmaru1524CF-Master Plus OP.

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 (K202116) and Ez3D-i (K200178). The sponsor tested the subject device in a laboratory and provided a non-clinical performance report. The same test protocol was used to test the performance of the subject and the predicate device for comparison. The sponsor certifies that adequate design and development controls (according to 21 CFR 820.30) were in place for manufacturing the subject device.

The subject device is equipped with a new detector, Xmaru1524CF Master Plus OP which captures an image in panoramic, CBCT and Model Scan mode.

Based on Non-Clinical Test results of the new detector Xmaru1524 Master Plus OP, the measured pixel sizes of the new sensor (Xmaru1524 Master Plus OP) are very similar to that of the predicate device (Xmaru1314CF). Therefore, compared to the predicate device, the test patterns of the new sensor images show the test subjects without aliasing phenomenon throughout the same spatial frequency as the predicate device. Moreover, the new Xmaru1524CF Master Plus OP sensor has performed similarly or better than the predicate device in terms of the overall DQE performance, given the DQE variation in low frequency (~ 0.5 lp/mm). At a low spatial frequency (~0.5 lp/mm), Xmaru1524CF Master Plus OP has the DQE of 41% (4x4binning) whereas Xmaru1314CF has 36% (4x4binning). The new sensor also exhibits similar performances in terms of MTF and NPS. In conclusion, the diagnostic image quality of the new sensor is equal or better than those of the predicate device and there is no significant difference in terms of efficiency and safety.

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 or better than 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 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 subject device and the predicate device has the same FDD(Focal Spot to Detector Distance) and exposure conditions (exposure time, tube voltage, tube current) was the same. DAP measurements compared at different FOV sizes (12x9/8x8/8x5/5x5 cm) were equivalent.

Moreover, the Clinical consideration and Image Quality Evaluation Report further demonstrated that the general image quality of the subject device is equivalent or better than 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.

Green X 18 (Model: PHT-75CHS) provides the following imaging viewer programs;

- 2D Image viewing program: EzDent-i(K202116)
- 3D Image viewing program: Ez3D-i(K200178)

- Safety, EMC and Performance Data

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1:2005+AMD1:2012(Edition 3.1), IEC 60601-1-3:2008+AMD1:2013 (Edition 2.1), IEC 60601-2-63:2012+AMD1:2017 (Edition 1.1) were performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2:2014 (Edition 4). The manufacturing facility is in conformance with the relevant EPRC standards as specified in 21 CFR 1020.30, 31, and 33 and the records are available for review. The Green X 18 (Model : PHT-75CHS) conforms to the provisions of NEMA PS 3.1-3.18, Digital Imaging and Communications in Medicine (DICOM) Set.

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

All test results were satisfactory.

10. Conclusions

Safety and effectiveness of the above hardware modifications 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. As demonstrated in the performance test, the Xmaru1524CF Master Plus OP performed equivalent or better in comparison with the predicate device in various performance parameters such as DQE, MTF and NNPS. In addition, image quality of new X-ray detector has been evaluated in compliance with IEC 61223-3-4 and IEC 61223-3-5. Both standard requirements were satisfied.

Quality assurance procedures are adhered to, and the specifications and functional requirements were met as the test results indicated.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, VATECH Co., Ltd. concludes that Green X 18 (Model: PHT-75CHS) is substantially equivalent to the predicate device as described herein.