Vatech Co., Ltd.
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7707 Fannin St., Ste. 200-V111
HOUSTON TX 77054

January 25, 2021

Re: K203797
Trade/Device Name: vatech A9 (Model: PHT-30CSS)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: December 18, 2020
Received: December 28, 2020

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,

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)*
K203797

Device Name
vatech A9(Model : PHT-30CSS)

Indications for Use *(Describe)*
vatech A9 (PHT-30CSS) is intended to produce panoramic, cone beam computed tomography, or cephalometric 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
K203797

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: January 11, 2021

3. Administrative Information

Official Correspondent: Dave Kim / Mtech Group
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Contact person: Mr. Dave Kim (davekim@mtech-inc.net)

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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:	vatech A9(Model : PHT-30CSS)
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:	Green16/Green18 (Model : PHT-65LHS)
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:	K170066

6. Device Description

vatech A9 (Model : PHT-30CSS) is an advanced 3-in-1 digital X-ray imaging system that incorporates PANO, CEPH (Optional), and CBCT scan imaging capabilities into a single system.

vatech A9 (Model : PHT-30CSS), a digital radiography imaging system, is specially designed to take X-ray images of patients on the chair and assist dentists.

Designed explicitly for dental radiography, vatech A9 (Model : PHT-30CSS) 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 and safety characteristics of the subject device are similar to the predicate device (PHT-65LHS(K170066)) and the reference device (PCH-30CS(K170731)).

The subject device has the same modalities and identical indications for use compared to the predicate device. In addition, the subject device uses the same image reconstruction algorithm and has similar FOV and DAP performance in CBCT mode. The subject device and the reference device use the same pano and ceph detector. Both devices have similar DAP measurements.

7. Indication for use

vatech A9 (Model : PHT-30CSS) is intended to produce panoramic, cone beam computed tomography, or cephalometric 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

	Subject Device	Predicate Device	Reference Device
Device Name	vatech A9 (Model : PHT-30CSS)	Green16/Green18 (Model : PHT-65LHS)	PaX-i Plus / PaX-i Insight (Model : PCH-30CS)
Applicant Name	VATECH Co., Ltd.	VATECH Co., Ltd.	VATECH Co., Ltd.
510(k) Number	N/A	K170066	K170731
Device Classification Name	X-Ray, Tomography, Computed, Dental	X-Ray, Tomography, Computed, Dental	System, X-Ray, Extra oral Source, Digital
Classification Product Code	OAS	OAS	MUH
Regulation Number	21 CFR 892.1750	21 CFR 892.1750	21 CFR 872.1800
Indications for Use	vatech A9 (Model : PHT-30CSS) is intended to produce panoramic, cone beam computed tomography, or cephalometric 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.	PHT-65LHS 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.	PCH-30CS is intended to produce panoramic or cephalometric 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 physicians, dentists, and x-ray technicians.
Performance Specification	Panoramic, Cephalometric and computed tomography	Panoramic, Cephalometric and computed tomography	Panoramic, Cephalometric
Input Voltage	AC 100 - 240 V	AC 100 - 240 V	AC 100 - 240 V
X-Ray source	D-054SB	D-052SB	D-052SB
Tube Voltage	60 - 99 kV	60 - 99 kV	60 - 99 kV
Tube Current	4 - 10 mA (for 60 - 99 kV) 4 - 12 mA (for 60 - 80 kV)	4 - 16 mA	4 - 10 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. 15.5 s	Max. 13.5 s	Max. 21 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 (K202116)	EzDent-i (K202116)	EasyDent(Cleared under K122155) EzDent-i (K202116)
3D Image Viewing Program	Ez3D-i (K200178)	Ez3D-i (K200178)	- -
Anatomical Sites	Maxillofacial	Maxillofacial	Maxillofacial

		Subject Device		Predicate Device		Reference Device	
Image Receptor	**CT&PANO**	Xmaru1404CF-PLUS		Xmaru1515CF		Xmaru1404CF-PLUS (PANO)	
				Xmaru1314CF		Xmaru1501CF-PLUS (PANO)	
	CEPH	Xmaru2602CF		Xmaru2602CF		Xmaru2602CF	
Size of Imaging Volume		Xmaru1404CF-PLUS	Max. 80 x 80 mm	Xmaru1515CF	Max. 180 x 100 mm	-	
				Xmaru1314CF	Max. 160 x 90 mm	-	
Pixel Resolution	**CT&PANO**	Xmaru1404CF-PLUS	5 lp/mm -2x2 binning (detector spec) 2.5 lp/mm -4x4 binning (system spec)	Xmaru1515CF	5 lp/mm -2x2 binning (detector spec) 2.5 lp/mm -4x4 binning (system spec)	Xmaru1501CF-PLUS	5 lp/mm
				Xmaru1314CF	5 lp/mm -2x2 binning (detector 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 (detector spec) 198 µm - 4X4 binning (system spec)	Xmaru1515CF	99 µm -2X2 binning (detector spec) 198 µm - 4X4 binning (system spec)	Xmaru1501CF-PLUS	100 µm
				Xmaru1314CF	99 µm -2X2 binning (detector 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)	
Dimension (Length x Width x Height) With Base	**With CEPH**	1938.9 (L) x 1173.3 (W) x 1716.0 (H) (mm)		1488.7 (L) x 1874.1 (W) x 2335.5 (H) (mm)		1910 (L) x 1200 (W) x 2300 (H) (mm)	
	Without CEPH	983.3 (L) x 1173.3 (W) x 1716.0 (H) (mm)		1488.7 (L) x1125 (W) x2335.5 (H) (mm)		990 (L) x 1200 (W) x 2300 (H) (mm)	
Weight (With Base)	**With CEPH**	130 kg (286.6 lbs.)		187 kg (412.3 lbs.)		135 kg (297.6 lbs.)	
	Without CEPH	156 kg (343.9 lbs.)		212 kg (467.4 lbs.)		160 kg (352.7 lbs.)	

9. Performance Data

- Summary of Performance Testing

The vatech A9 (Model : PHT-30CSS) digital X-ray system described in this 510(k) is similar to the predicate device in terms of indications for use, materials and safety characteristics.

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 modes are identical; CBCT, PANO and CEPH (Optional). 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.

For both devices, the differences are as follows.

a. The subject device is equipped with the Xmaru1404CF-PLUS detector which has been cleared with previous 510k submissions, PCH-30CS (K170731).
b. The specification for both D-054SB and D-052SB x-ray source (tube) is the same as confirmed by the maximum rating charts, emission & filament characteristics. The model name, D-054SB, is designated to indicate its NMPA approval according to the company's business strategic plan.
c. The physical appearance of the subject device is different in comparison with the predicate device. Both the height and the weight of the subject device have been reduced by about 600 mm and about 50 kg, respectively.

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 CS(iterative) reconstruction algorithm for the new X-ray equipment. The results demonstrated that the general image quality of the subject device is equivalent or better than the predicate device.

In addition, the dosimetry performance of the subject device, reference device and the predicate device was compared in terms of DAP. The subject device's Panoramic mode uses the same detector and exposure area compared to the reference device, but there is a difference in FDD (Focal Spot to Detector Distance). The FDD of the reference device (PCH-30CS) is 490.3 mm whereas the FDD for PHT-30CSS is 584.6 mm. The dose decreases by about 25~30% as the FDD increases under the same exposure conditions. The mA setting for the subjective device was increased to be in line with the DAP of the predicate device in the Normal Panoramic mode.

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 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 FDD, exposure area and exposure time. Considering these differences, the FOV 80x80mm of PHT-30CSS and the FOV 80 x 90 mm of PHT-65LHS have been compared. The FOV size of PHT-65LHS was transposed from FOV 80x90 mm to FOV 80x80 mm, the outcome result confirmed that the CBCT mode for both devices performed similarly.

Moreover, PANO/CEPH/CBCT images from the subject and predicate device are evaluated in the Image Quality Evaluation Report. The results 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, "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.

vatech A9 (Model: PHT-30CSS) 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 vatech A9 (Model : PHT-30CSS) 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 hardware modifications and additional software functions have been clarified through each verification. Each software function has already been incorporated in previous devices which obtained premarket clearance by FDA and widely used in the market. Additional performance testing has been conducted for the subject device and all testing outcomes met the acceptance performance criteria 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 similar indications for use and demonstrated similar technical characteristics. As demonstrated in the performance test, 1) Xmaru1404CF-PLUS was previously cleared by the reference device, PCH-30CS (K170731), 2) The specification of D-054SB tube has the same maximum rating charts, emission & filament characteristics as D-052SB of the predicate device. Furthermore, image quality of new X-ray detector and X-ray source 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 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 vatech A9(Model: PHT-30CSS) is

substantially equivalent to the predicate device as described herein.