October 26, 2022

VATECH Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7505 Fannin Street, Suite 610
HOUSTON TX 77054

Re: K223058
Trade/Device Name: EzRay Air 2 Wall (Model: VEX-S350W)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: September 22, 2022
Received: September 30, 2022

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,

Laurel Burk, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223058

Device Name
EzRay Air 2 Wall (Model: VEX-S350W)

Indications for Use *(Describe)*
The EzRay Air 2 Wall (Model Name: VEX-S350W) is a dental X-ray system intended for use by a trained and qualified dentist or dental technician for both adult and pediatric subjects for producing diagnostic dental radiographs for the treatment of diseases of the teeth, jaw, and other oral structures using intra-oral image receptors.

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

K223058

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: October 20, 2022

3. Administrative Information

Official Correspondent:	Dave Kim / Mtech Group Address: 7505 Fannin Street, Suite 610, Houston, TX 77025 Tel: +713-467-2607 Contact person: Mr. Dave Kim (davekim@mtech-inc.net)
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.com)

4. Device Information

Type of 510(k) Submission:	Special
Trade or Proprietary Name:	EzRay Air 2 Wall (Model: VEX-S350W)
Common or Usual Name:	Dental X-ray system
Regulation Classification:	Extraoral source X-ray system (21 CFR 872.1800)
Product Code:	EHD
Class of Device:	Class II
Panel:	Radiology

5. Predicate Device Information

Manufacturer:	VATECH Co., Ltd.
Predicate device:	EzRay Air Wall (Model: VEX-S300W) / K163705
Common or Usual Name:	Dental X-ray system
Regulation Classification:	Extraoral source X-ray system (21 CFR 872.1800)
Product Code:	EHD
Class of Device:	Class II
Panel:	Radiology

6. Device Description

The EzRay Air 2 Wall (Model: VEX-S350W) is a dental X-ray system intended for intra-oral imaging. It consists of an X-ray generator, X-ray controller, beam limiting device, operation panel, and mechanical arm. The X-ray controller allows for accurate exposure control, and the adjustable mechanical arm allows for easy positioning. The functions of the VEX-S350W intra-oral system are supported by software (firmware). The software is based on the predicate device and is of Moderate level of concern. The system can be used with an imaging system.

7. Indication for use

The EzRay Air 2 Wall (Model Name: VEX-S350W) is a dental X-ray system intended for use by a trained and qualified dentist or dental technician for both adult and pediatric subjects for producing diagnostic dental radiographs for the treatment of diseases of the teeth, jaw, and other oral structures using intra-oral image receptors.

8. Substantial Equivalence Chart

		Subject Device	Predicate Device
Device Name		EzRay Air 2 Wall (Model: VEX-S350W)	EzRay Air Wall (Model: VEX-S300W)
Applicant Name		VATECH Co., Ltd.	VATECH Co., Ltd.
510(k) Number		N/A	K163705
Device Classification Name		Extraoral source x-ray system	Extraoral source x-ray system
Classification Product Code		EHD	EHD
Regulation Number		21 CFR 872.1800	21 CFR 872.1800
Indications for Use		The EzRay Air 2 Wall (Model: VEX-S350W) is a dental X-ray system intended for use by a trained and qualified dentist or dental technician for both adult and pediatric subjects for producing diagnostic dental radiographs for the treatment of diseases of the teeth, jaw, and other oral structures using intra-oral image receptors.	The EzRay Air W (Model: VEX-S300W) is an intra-oral dental X-ray system (extra-oral X-ray source system) intended for use by a trained and qualified dentist or dental technician for both adult and pediatric subjects for producing diagnostic dental radiographs for treatment of diseases of the teeth, jaw, and other oral structures using intra-oral image receptors.
Mechanical	**Minimum Source to skin distance**	200 mm	200 mm
	X-ray field Size (default)	60 mm round	60 mm round
	Focal spot	0.4 mm	0.4 mm
	Minimum half-value layer	1.5 mm Al	1.5 mm Al
Electrical	**Electric Power Voltage**	AC 100-240 V	AC 100-240 V
	Rated Current	10 A (at AC 250 V)	10 A (at AC 250 V)
	Exposure time	0.05 - 2.0 seconds in 0.01 increments	0.05 - 0.5 seconds in 0.01 increments
	Tube current	5.0 mA fixed	2.5 or 3.0 mA fixed
	Tube voltage	65 / 70 kVp fixed	65 kVp fixed
	Operation mode	Manual Mode	Manual Mode, Auto Mode
	Applied Standard	IEC 60601-1, IEC 60601-1-3, IEC 60601-2-65, IEC 60601-1-2, 21 CFR 1020.30, 1020.31	IEC 60601-1, IEC 60601-1-3, IEC 60601-2-65, IEC 60601-1-2, 21 CFR 1020.30, 1020.31

9. Performance Data

- Summary of Performance Testing

The performance test for the subject device, EzRay Air 2 Wall (Model: VEX-S350W) and the predicate device, VEX-S300W (K163705) confirmed that the focal spot to skin distance for both devices was longer than the minimum length of 20 cm. Accuracy of loading factors and reproducibility of Air KERMA for both X-ray systems also met the essential performance requirements (ex. < kVp +10 %). Both devices demonstrated similar performance outcomes in terms of HVL (half-value layer) and limitation of the x-ray field test which rendered satisfactory X-ray performance results in accordance with Federal Standard (21CFR 1020.30 and 31) requirements.

- Safety, EMC and Performance Data

The subject device complies with the safety and performance standards listed in the chart above, 'Substantial Equivalence Chart'.

Electrical, mechanical, environmental safety, and performance testing according to standard IEC 60601-1(Ed. 3.1, 2012), IEC 60601-1-3 (Ed. 2.1, 2013), IEC 60601-2-65 (Ed. 1.1, 2017) were performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2.

Test reports were provided to demonstrate conformance. All test results complied with the requirements.

10. The differences between the subject device and the predicate device

The EzRay Air 2 Wall (Model: VEX-S350W) described in this special 510(k) is similar to the predicate device in its indications for use, design, technology, functions, and principle of operation. The differences between the subject device and the predicate device are as follows:
The predicate device (EzRay Air Wall (Model: VEX-S300W) - K163705) is optimized for a digital sensor as an imaging receptor but EzRay Air 2 Wall (Model: VEX-S350W) can be used with a digital sensor or a phosphor plate as an imaging receptor according to the user's preference. For the user of a phosphor plate, EzRay Air 2 Wall (Model: VEX-S350W) provides increased tube voltage, tube current, and irradiation time compared to the predicate device. The tube voltage can be selected as either 65/70 kVp and the tube current is fixed at 5.0 mA The irradiation time has been increased up to 2.0 sec.
Based on the increased irradiation conditions, electrical safety and EMC test have been conducted.
The performance of the EzRay Air 2 Wall (Model: VEX-S350W) was tested through Accuracy of loading factors, HVL, limitation of the x-ray field, reproducibility of Air KERMA, and Linearity of AIR KERMA. All test results are in compliance with Federal Standard (21CFR 1020.30 and 31) requirements.

A digital sensor and phosphor plate were used to verify the image performance for each image receptor. The image performance was evaluated with low contrast and line pair according to the IEC standard through performance bench testing.

The Performance Bench Testing demonstrated that these differences do not raise new questions of safety and effectiveness in comparison with the predicate device.

11. Conclusions

The subject device and the predicate device have similar indications for use and demonstrated similar design, technology, functions, and principle of operation. As demonstrated in the performance bench testing, X-ray safety and performance and Image evaluation of the new and predicate devices were tested in accordance with Federal Standard 21CFR Part 1020.30 and 31 as well as international standards such as IEC 60601-1, 60601-2-65, and 61223-3-4. Both the subject and predicate devices met the essential performance parameters including accuracy of loading factors, Reproducibility of Air KERMA, Focal Spot to Skin Distance, and Low Contrast & Line Pair performance requirements.

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 EzRay Air 2 Wall (Model: VEX-S350W) is substantially equivalent to the predicate device as described herein.