DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 1, 2016

Vatech Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

Re: K161063
Trade/Device Name: EzRay Air (Model VEX-P300)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: July 19, 2016
Received: July 26, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161063

Device Name
EzRay Air
VEX-P300

Indications for Use *(Describe)*
VEX-P300 is an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors. It is indicated for use by a dentist or a dental technician for both adult and pediatric patients.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5 – 510(k) Summary

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: July 15, 2016

3. Administrative Information

Official Correspondent:	Dave Kim / Mtech Group Address: 12946 Kimberley Ln, Houston, TX 77079 Tel: +713-467-2607 Fax: +713-464-8880 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.co.kr)

4. Device Information

Type of 510(k) Submission:	Traditional
Trade or Proprietary Name:	EzRay Air (Model: VEX-P300)
Common or Usual Name:	Portable 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:	Aribex, Inc.
Trade or Proprietary Name:	NOMAD Pro X-ray System
Common or Usual Name:	Portable X-ray System
Regulation Classification:	Extraoral source x-ray system (21 CFR 872.1800)
Product Code:	EHD
Class of Device:	Class II
Panel:	Radiology
510(k) Number:	K081664

6. Device Description

VEX-P300, a portable dental X-ray system, operates on 22.2V DC supplied by a rechargeable Li-ion polymer battery pack. The portable x-ray system is an x-ray generating device which is mainly designed for dental examination (teeth and jaw). The portable X-ray system is composed of an x-ray generating part with an x-ray tube including a device controller, a power controller, a user interface, a beam limiting part, a back scattering shield, and an optional remote exposure switch. VEX-P300 is designed to diagnose tooth and jaw through X-ray exposure using intraoral image receptors.

7. Indication for use

VEX-P300 is an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors. It is indicated for use by a dentist or a dental technician for both adult and pediatric patients.

8. Substantial Equivalence Chart

		Subject Device	Predicate Device
Device Name		EzRay Air(Model: VEX-P300)	NOMAD Pro X-ray System
Applicant Name		VATECH Co., Ltd.	Aribex, Inc.
510(k) Number		N/A	K081664
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		VEX-P300 is an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors. It is indicated for use by a dentist or a dental technician for both adult and pediatric patients.	The NOMAD Pro X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.
Mechanical	**Size (L x W x H)**	280 x 165 x 296 mm	266.7 x 133.35 x 304.8 mm
	Source to skin distance	200 mm	210 mm
	X-ray field Size	60 mm round	60 mm round
	User Interface	Jog dial for operating mode selection. Additionally, several user-selectable preset times with patient size and tooth selection icons on a display module.	Up-down buttons for exposure time selection, with timer display. Additionally, several user-selectable preset times with patient size, image-receptor type, and tooth selection icons on an LCD display.
	Backscatter radiation protection	165 mm dia., Pb-filled acrylic plastic, Back Scattering shield	171.45 mm dia. Pb-filled acrylic plastic scatter shield
	Exposure Switch	Exposure button on the handset	Trigger on Handset
	Tube head mounting	Handheld	Handheld
Electrical	**Energy source**	Rechargeable 22.2 V DC Li-ion polymer battery pack	Rechargeable 22.2 V DC Lithium Polymer battery pack
	Exposure time	0.05 - 0.5 seconds in 0.01 increments	0.02 - 1.00 seconds in 0.01 increments
	mA	2.5 mA fixed	2.5 mA fixed
	kVp	60 or 65 kVp fixed	60 kVp fixed
	Waveform	Constant Potential (DC)	Constant Potential (DC)
	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, EN 60601-1, EN 60601-1-2, IEC 60601-1-3, IEC 60601-2-7, 21 CFR 1020.30, 1020.31

9. Performance Data

- Summary of Performance Testing

The performance test for the subject device, VEX-P300 and the predicate device, NOMAD Pro X-ray System (K081664) confirmed that the focal spot to skin distance for both devices were 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, limitation of the x-ray field and leakage radiation 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'. Test reports were provided to demonstrate conformance. All test results were complied with the requirements.

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

The VEX-P300 Portable X-ray system described in this traditional 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:

① Device Size

Subject device-280 x 165 x 296 mm
Predicate device-266.7 x 133.35 x 304.8 mm

② SSD

Subject device-200 mm
Predicate device-210 mm

③ Backscatter radiation protection size (diameter):

Subject device-165 mm dia.
Predicate device-171.45 mm dia.

④ Exposure time

Subject device-0.05 - 0.5 seconds in 0.01 increments
Predicate device-0.02 - 1.00 seconds in 0.01 increments

⑤ Tube voltage (kVp), Tube current(mA)

Subject device-2.5 mA fixed, 60 or 65 kVp fixed
Predicate device-2.5 mA fixed, 60 kVp fixed

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 performance and X-ray Safety 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, Leakage radiation, and Low Contrast & Line Pair performance requirements.
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 VEX-P300 is substantially equivalent to predicate device as described herein.