DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 24, 2017

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

Re: K163705
Trade/Device Name: EzRay Air W (Model: VEX-S300W)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: December 23, 2016
Received: December 29, 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)*

K163705

Device Name
EzRay Air W (Model: VEX-S300W)

Indications for Use *(Describe)*

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.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# Section 7 – 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:** December 09, 2016

**3. Administrative Information**

| | |
|---|---|
| **Official Correspondent:** | Dave Kim / Mtech Group<br>Address: 8310 Buffalo Speedway, Houston, TX 77025<br>Tel: +713-467-2607<br>Fax: +713-464-8880<br>Contact person: Mr. Dave Kim (davekim@mtech-inc.net) |
| **510(k) Submitter:** | VATECH Co., Ltd.<br>Address: 13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449, Korea<br>Tel: +82-31-379-9492<br>Fax: +82-31-379-9400<br>Contact person: Daniel Kim / Manager (daniel.kim@vatech.co.kr) |

**4. Device Information**

| | |
|---|---|
| **Type of 510(k) Submission:** | Special |
| **Trade or Proprietary Name:** | EzRay Air W (Model: VEX-S300W) |
| **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:** | VEX-S100W / K123493 |
| **Reference device:** | EzRay Air (Model: VEX-P300) / K16063 |
| **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 W (Model: VEX-S300W) is an intra-oral dental X-ray system intended for intra-oral imaging. It consists of 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 system can be used with an imaging system.

## 7. Indication for use

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.

**8. Substantial Equivalence Chart**

| | | Subject Device | Predicate Device | Reference Device |
|---|---|---|---|---|
| **Device Name** | | EzRay Air W (Model: VEX-S300W) | VEX-S100W | EzRay Air (Model: VEX-P300) |
| **Applicant Name** | | VATECH Co., Ltd. | VATECH Co., Ltd. | VATECH Co., Ltd. |
| **510(k) Number** | | N/A | K123493 | K161063 |
| **Device Classification Name** | | Extraoral source x-ray system | Extraoral source x-ray system | Extraoral source x-ray system |
| **Classification Product Code** | | EHD | EHD | EHD |
| **Regulation Number** | | 21 CFR 872.1800 | 21 CFR 872.1800 | 21 CFR 872.1800 |
| **Indications for Use** | | 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. | The VEX-S100W is an extraoral source of X-rays, intended to be used for producing diagnostic dental radiographs for treatment of disease of the teeth, jaw and oral structures. | 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. |
| **Mechanical** | **Minimum Source to skin distance** | 200 mm | 1) 200 mm (default)<br>2) 300 mm (option) | 200 mm |
| | **X-ray field Size (default)** | 60 mm round | 60 mm round | 60 mm round |
| | **Focal spot** | 0.4 mm | 0.4 mm | 0.4 mm |
| | **Minimum half-value layer** | 1.5 mm Al | 1.5 mm Al | 1.5 mm Al |
| **Electrical** | **Electric Power Voltage** | AC 100-240 V | AC 100-120 V / 200 -240 V | Rechargeable 22.2 V DC Li-ion polymer battery pack |
| | **Rated Current** | 10 A (at AC 250 V) | 16 A (at AC 250 V) | N/A |
| | **Exposure time** | 0.05 - 0.5 seconds in 0.01 increments | 0.04 - 2.0 seconds in 0.01 increments | 0.05 - 0.5 seconds in 0.01 increments |
| | **Tube current** | 2.5 or 3.0 mA fixed | 4 - 7 mA | 2.5 mA fixed |
| | **Tube voltage** | 65 kVp fixed | 50 - 70 kVp | 60 or 65 kVp fixed |
| | **Operation mode** | Manual Mode, Auto Mode | Manual Mode | Manual Mode, Auto Mode |
| | **Applied Standard** | IEC 60601-1,<br>IEC 60601-1-3,<br>IEC 60601-2-65,<br>IEC 60601-1-2,<br>21 CFR 1020.30, 1020.31 | IEC 60601-1,<br>IEC 60601-1-3,<br>IEC 60601-2-65,<br>IEC 60601-1-2,<br>21 CFR 1020.30, 1020.31 | IEC 60601-1,<br>IEC 60601-1-3,<br>IEC 60601-2-65,<br>IEC 60601-1-2,<br>21 CFR 1020.30, 1020.31 |

## 9. Performance Data

**- Summary of Performance Testing**

The performance test for the subject device, EzRay Air W (Model: VEX-S300W) and the predicate device, VEX-S100W (K123493) 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 (half-value layer), 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.

The safety and effectiveness of Auto Mode function have been demonstrated and confirmed by the previous 510k submission of the reference device, EzRay Air (Model: VEX-P300) (K16063).

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

The EzRay Air W (Model: VEX-S300W) extraoral source x-ray system 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:

1) Electric Power Voltage, Rated Current
Subject device- AC 100-240 V, 10 A (at AC 250 V)
Predicate device- AC 100-120 V / 200 -240 V, 16 A (at AC 250 V)
2) Exposure time
Subject device-0.05 - 0.5 seconds in 0.01 increments
Predicate device- 0.04 - 2.0 seconds in 0.01 increments
3) Tube voltage (kVp), Tube current (mA)
Subject device- 2.5 or 3.0 mA fixed, 65 kVp fixed
Predicate device- 4 - 7 mA, 50 - 70 kVp
4) Dial Type Control Panel
The control panel setting is done with a dial button which makes to increase an ease to use and reduce the time for preparation. Operators need to control only one dial button for capture mode settings such as selection of Adult/Child & Tooth Mode. This control panel design is same with EzRay Air (Model: VEX-P300), the reference device (K161063)
5) Smart Position
The smart positioning makes extremely simple preparation. Operators only set the guideline following occlusal plane or frankfurt line. Then, it automatically detects an angle and a tooth. According to the setting by smart positioning, it changes exposure time as well. This feature is identical to EzRay Air (Model: VEX-P300), the reference device (K161063)

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.

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 W (Model: VEX-S300W) is substantially equivalent to predicate device as described herein.