Vatech Co., Ltd.
℅ Mr. Dave Kim
Medical Device Regulatory Affairs
MtechGroup
7707 Fannin St., Ste. 200-V111
HOUSTON TX 77054

February 11, 2020

Re: K200182
Trade/Device Name: EzRay Air Portable (Model: VEX-P300)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: January 21, 2020
Received: January 24, 2020

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K200182

Device Name
EzRay Air Portable (Model: VEX-P300)

Indications for Use *(Describe)*
EzRay Air Portable (Model: 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
# K200182

**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:** January 21, 2020

**3. Administrative Information**

| | |
|---|---|
| **Official Correspondent:** | Dave Kim / Mtech Group<br>Address: 7707 Fannin St., Ste. 200-V111, Houston, TX 77054<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 Portable (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:** | VATECH Co., Ltd. |
| **Trade or Proprietary Name:** | EzRay Air Portable (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 |
| **510(k) Number:** | K161063 |

## 6. Device Description

EzRay Air Portable (Model: VEX-P300), a portable dental X-ray system, operates on 21.6V 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. EzRay Air Portable (Model: VEX-P300) is designed to diagnose tooth and jaw through X-ray exposure using intraoral image receptors.

The device software is the same as the predicate device.

## 7. Indication for use

EzRay Air Portable (Model: 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 Portable (Model: VEX-P300) | EzRay Air Portable (Model: VEX-P300) |
| **Applicant Name** | | VATECH Co., Ltd. | VATECH Co., Ltd. |
| **510(k) Number** | | N/A | K161063 |
| **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** | | EzRay Air Portable (Model: 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. | 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** | **Size (L x W x H)** | 280 x 165 x 296 mm | 280 x 165 x 296 mm |
| | **Source to skin distance** | 200 mm | 200 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. | Jog dial for operating mode selection. Additionally, several user-selectable preset times with patient size and tooth selection icons on a display module. |
| | **Backscatter radiation protection** | 165 mm dia., Pb-filled acrylic plastic, Back Scattering shield | 165 mm dia., Pb-filled acrylic plastic, Back Scattering shield |
| | **Exposure Switch** | Exposure button on the handset | Exposure button on the handset |
| | **Tube head mounting** | Handheld | Handheld |
| **Electrical** | ***Energy source*[1]** | Rechargeable 21.6 V DC Li-ion polymer battery pack (Nominal Capacity: 2,500 mAh) | Rechargeable 22.2 V DC Li-ion polymer battery pack (Nominal Capacity: 1,000 mAh or 900 mAh) |
| | ***Exposure time*[2]** | 0.05 - 1.0 seconds in 0.01 increments | 0.05 - 0.5 seconds in 0.01 increments |
| | **mA** | 2.5 mA fixed | 2.5 mA fixed |
| | **kVp** | 60 or 65 kVp fixed | 60 or 65 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, IEC 60601-1-3, IEC 60601-2-65, IEC 60601-1-2, 21 CFR 1020.30, 1020.31 |

**Note: The differences between the subject device and the predicate device, No. 1 and 2, are discussion in the Section 10 below.**

## 9. Performance Data

**- Summary of Performance Testing**

The performance test for the subject device, EzRay Air Portable (Model: VEX-P300)and the predicate device, VEX-P300 (K161063) 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

EzRay Air Portable (Model: VEX-P300) described in this special 510(k) is same as the predicate device in its indications for use, design, technology, functions, and principle of operation. The differences are as follows:

① Energy source

Subject device-Rechargeable 21.6 V DC Li-ion polymer battery pack (Nominal Capacity: 2,500 mAh)
Predicate device-Rechargeable 22.2 V DC Li-ion polymer battery pack (Nominal Capacity: 1,000 mAh or 900 mAh)

EzRay Air Portable (Model: VEX-P300)receives power from the built-in rechargeable Li-ion polymer battery pack. The batter pack has been updated to 21.6 V DC compared to the 22.2 V DC of the predicate device (K161063). The battery's nominal capacity has also been increased from 1,000 mAh to 2,500 mAh to take more radiographic images per charge. Rechargeable 21.6 V DC Li-ion polymer battery pack with increased capacity has been tested and is in conformity with the standard IEC 62133(Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications )

② Exposure time

Subject device-0.05 - 1.0 seconds in 0.01 increments
Predicate device-0.05 - 0.5 seconds in 0.01 increments

The irradiation time of EzRay Air Portable (Model: VEX-P300), the subject device, ranges 0.05~1.0 seconds compared to 0.05-0.5 seconds for the predicate device (EzRay Air Portable (Model: VEX-P300) – K161063). The increase of the maximum exposure time by 0.5 seconds would enable the users to choose a phosphor plate as well as a digital sensor as an intra oral X-ray receptor for convenience. The performance of the increased irradiation time has been tested and validated through the following tests: Accuracy of loading factors, HVL and Total filtration, limitation of the x-ray field, reproducibility of Air KERMA, Linearity of AIR KERMA and leakage radiation test. All test results are in compliance with Federal Standard (21CFR 1020.30 and 31) requirements.

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 same 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 EzRay Air Portable (Model: VEX-P300) is substantially equivalent to predicate device as described herein.