February 11, 2022

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

Re: K213462
Trade/Device Name: EzRay M18 (Model: VMX-P400)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: January 7, 2022
Received: January 13, 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
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)*
K213462

Device Name
EzRay M18 (Model: VMX-P400)

Indications for Use *(Describe)*
EzRay M18 (Model: VMX-P400) is a portable X-ray system, intended for use by a qualified/trained physician or technician to acquire X-ray images of the desired parts of a patient's anatomy on adult and pediatric patients (including head, chest, abdomen, cervical spine, and extremities).
The device may be used for handheld diagnostic imaging of body extremities.
The system is subject to the following limitations of use when stand-mounted:
- The device may be used for diagnostic imaging of the head, abdomen, cervical spine, or extremities.
- The device may be used for imaging of the chest when used without a grid.
This device is not intended for mammography.

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
K213462

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 7, 2022

3. Administrative Information

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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:	Traditional
Trade or Proprietary Name:	EzRay M18 (Model: VMX-P400)
Common or Usual Name:	Medical Portable X-ray System
Regulation Classification:	Mobile X-ray system (21 CFR 892.1720)
Product Code:	IZL
Class of Device:	Class II
Panel:	Radiology

5. Predicate Device Information

Manufacturer:	MinXray, Inc.
Trade or Proprietary Name:	TR90BH
Common or Usual Name:	Mobile Diagnostic X-Ray System
Regulation Classification:	Mobile X-ray system (21 CFR 892.1720)
Product Code:	IZL
Class of Device:	Class II
Panel:	Radiology
510(k) Number:	K 182207

6. Reference Device Information

Manufacturer:	OSKO, Inc.
Trade or Proprietary Name:	XR5
Common or Usual Name:	Stationary x-ray system
Regulation Classification:	Stationary x-ray system (21 CFR 892.1680)
Product Code:	KPR
Class of Device:	Class II
Panel:	Radiology
510(k) Number:	K150663

7. Device Description

EzRay M18 (Model: VMX-P400), a medical portable X-ray system, operates on 57.6 Vdc supplied by a rechargeable Li-ion battery pack. The system is composed of an X-ray generating part including an X-ray tube, a device controller, a power controller, a user interface, a beam limiting part, and two optional components: remote controller and stand. The device software supports the functions of the EzRay M18 system, and the software is of Moderate level of concern. The device is designed for the diagnosis of the human body using image receptors. The image detectors, a necessary component for a fully-functional x-ray system, are not part of this submission.

8. Indications for use

EzRay M18 (Model: VMX-P400) is a portable X-ray system, intended for use by a qualified/trained physician or technician to acquire X-ray images of the desired parts of a patient's anatomy on adult and pediatric patients (including head, chest, abdomen, cervical spine, and extremities).
The device may be used for handheld diagnostic imaging of body extremities.
The system is subject to the following limitations of use when stand-mounted:
- The device may be used for diagnostic imaging of the head, abdomen, cervical spine, or extremities.
- The device may be used for imaging of the chest when used without a grid.

This device is not intended for mammography.

9. Substantial Equivalence Chart

	Subject Device	Predicate Device	Reference Device
Device Name	EzRay M18 (Model: VMX-P400)	TR90BH	XR5
Applicant Name	VATECH Co., Ltd.	MinXray, Inc.	OSKO, INC.
510(k) Number	K213462	K182207	K150663
Device Classification Name	Mobile X-ray system	Mobile X-ray system	Stationary X-ray system
Classification Product Code	IZL	IZL	KPR
Regulation Number	21 CFR 892.1720	21 CFR 892.1720	21 CFR 892.1680
Regulation Class	II	II	II
Indications for Use	EzRay M18 (Model: VMX-P400) is a portable X-ray system, intended for use by a qualified/trained physician or technician to acquire X-ray images of the desired parts of a patient's anatomy on adult and pediatric patients (including head, chest, abdomen, cervical spine, and extremities). The device may be used for handheld diagnostic imaging of body extremities. The system is subject to the following limitations of use when stand-mounted: - The device may be used for diagnostic imaging of the head, abdomen, cervical spine, or extremities. - The device may be used for imaging of the chest when used without a grid. This device is not intended for mammography.	The TR90BH is a portable X-ray system with following limitations of use: The device may be used for handheld diagnostic imaging of body extremities The device may be used for stand mounted diagnostic imaging of head, abdomen, or extremities. The device may be used for stand mounted imaging of the chest when used without a grid. - Not to be used on bariatric patients, unless imaging body extremities - Not for mammography use - The TR90BH is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.	The XR5 diagnostic X-ray system is intended for use on adult and pediatric patients for taking diagnostics radiographic exposure of all body parts and operated by a qualified/trained doctor or technician. The XR5 diagnostic X-ray system is designed to be used with conventional film/screen, CR cassettes or digital detectors. NOT intended for Mammography use.

Technological	**Size: Body**	214 x 305 x 309 mm (excluding Skin Distance Bar)	219 x 442 x 190 mm	1,940 mm (Tube stand height), 1,480 mm (Vertical movement), 2,540 mm (Longitudinal movement)
	Weight	5.88 kg	7.5 kg	-
	Collimator	Four manually and steplessly adjustable shutters with LED Light x-ray field indicator	Mikasa BLD34L	Manual (K062788)
	User Interface	Soft touch push buttons	Soft touch push buttons	push buttons
	Energy source	Rechargeable 57.6 V DC Li-ion battery pack	Lithium-ion Rechargeable Battery (57.6DC), 300 exposures per charge.	110-220 VAC
	Exposure times	0.02 sec – 2.0 sec: R'20 sec Step (Exposure conditions follow R'20 in combination of mAs)	0.01 sec – 1.0 sec : 0.01 sec Step High Power Mode 0.01 sec – 0.3 sec : 0.01 sec Step	6.3 sec Max.
	mA	20 mA @ 40 – 90 kV (1 kV steps) 15 mA @ 61 – 90 kV (1 kV steps) 10 mA @ 81 – 90 kV (1 kV steps)	20 mA @ 40 kVDC – 60 kVDC (2 kVP steps) 15 mA @ 62 kVDC – 80 kVDC (2 kVP steps) 10 mA @ 82 kVDC – 90 kVDC (2 kVP steps) High Power Mode 15 mA @ 82 kVDC – 90 kVDC (2 kVP steps)	10 – 500 mA
	Memory settings	10 memories via pushbutton	5 memories via pushbutton	No
	HF Generator	High Frequency	High Frequency	High Frequency
	kW	1.8 kW	1.35 kW	40 kW
	kVp	40 – 90kVp	40 – 90kVp	40-125 kVp
	X-ray Tube	D-0814	D-0814	E7239x
FDA Performance Standard		Complies	Complies	Complies

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

The subject device described in this traditional 510(k) is similar to the predicate device (K182207) in its indications for use and technological application. Both the subject and predicate devices are taking diagnostic X-rays using a variable tube voltage (kVp) and current time product (mAs) or exposure time.
The collimator of the EzRay M18 device is a continuously adjustable light beam type similar to the predicate TR90BH. The user can irradiate X-ray by adjusting the X-ray filed size to the size of the desire body part. Exposure parameters are similar for both EzRay M18 and TR90BH using the same Canon X-ray tube model D-0814. However, EzRay 18 has a larger capacity of the X-ray mono tank within the X-ray tube spec, resulting in higher exposure output. The high power mode of the predicate device, TR90BH, is 15 mA, the output (kW) is 1.35 kW for the maximum tube voltage 90kV. EzRay M18 emits a maximum of 20 mA and the output of 1.8 kW when the maximum tube voltage is 90kV. Because EzRay M18 is capable of setting a higher mA under the same maximum tube voltage of 90kV, it is possible to capture radiographic images of the same body parts intended for the predicate device. For the energy source, battery pack, the subject device receives power from the built-in rechargeable Li-ion battery pack which as same as the predicate device (K182207) uses. Rechargeable Li-ion battery pack has been tested and is in conformity with the standard IEC 62133. Other differences include device design such as exposure time, size and user interface.

10. Non clinical Testing

Testing was performed successfully according to the following standards:

- IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012
- IEC 60601-1-2:2014
- IEC 60601-1-3:2008 (Second Edition) + A1:2013
- IEC 60601-2-28:2017
- IEC 60601-2-54:2009, AMD1:2015, AMD2:2018
- IEC 62133-2:2017

Furthermore, the following Specific Guidance Document was utilized in the device development to ensure the safety of this device for both the operators and patients:
"The Content of Premarket Submissions for Software Contained in Medical Devices"
"Radiation Safety Consideration for X-ray Equipment Designed for Hand-Held Use"

The device also conforms to the following:
21 CFR 1020 Subchapter J: Performance Standards for Ionizing Radiation Emitting Products
21 CFR 1020.30: Diagnostic x-ray system and their major components
21 CFR 1020.31: Radiographic Equipment

Image performance testing was performed on the EzRay M18 in comparison with a reference device XR5 (K150663) using a FDA-cleared flat-panel detector, 1417WCC (K171418). The results of MTF, spatial frequency, DQE and NPS were compared under the same exposure conditions. The results demonstrated that the general image performance of the subject device is equivalent to the reference device. The difference between the two devices is that EzRay M18 is a portable X-ray system whereas the reference device is a stationary diagnostic X-ray system. It is concluded that EzRay M18 demonstrated adequate image quality performance through comparative study with the reference device.

11. Conclusions

In reference to the comparison information provide in Substantial Equivalence Chart, the subject device and the predicate device have little difference with its technological features. As demonstrated in the performance bench testing, X-ray performance and X-ray Safety of the subject device was tested in accordance with Federal standard 21CFR Part 1020.30 and 31 as well as international standards such as IEC 60601-1, 60601-2-54. 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 M18 (Model: VMX-P400) is substantially equivalent to the predicate device and its image quality performed equivalently in comparison with XR5 (K150663) using 1417WCC, a FDA-cleared digital detector (K171418) under the same exposure condition.