Vatech Co., Ltd.
℅ Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7707 Fannin Street, Suite 200-Vlll
HOUSTON TX 77054

February 2, 2021

Re: K203667
Trade/Device Name: EzRay M (Model: VMX-P300)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: December 10, 2020
Received: December 16, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203667

Device Name
EzRay M (Model: VMX-P300)

Indications for Use *(Describe)*
EzRay M (Model: VMX-P300) is a portable general-purpose X-ray system that users can operate with one hand. The device uses a fixed tube current and voltage (kVp) and, therefore, is limited to taking diagnostic X-rays of extremities. It is intended to be used by a qualified and trained clinician on adult patients. It is not intended to replace a radiographic system with variable tube current and voltage (kVp), which may be required for full optimization of image quality and radiation exposure for different exam types.

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
K203667

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: January15, 2021

3. Administrative Information

Official Correspondent:	Dave Kim / Mtech Group Address: 7707 Fannin St., Ste. 200-V111, Houston, TX 77054 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:	Traditional
Trade or Proprietary Name:	EzRay M (Model: VMX-P300)
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:	Aribex, Inc.
Trade or Proprietary Name:	NOMAD MD Handheld X-ray System
Common or Usual Name:	Nomad MD
Regulation Classification:	Mobile X-ray system (21 CFR 892.1720)
Product Code:	IZL
Class of Device:	Class II
Panel:	Radiology
510(k) Number:	K140723

6. Device Description

EzRay M (Model: VMX-P300), a medical portable X-ray system, operates on 21.6 Vdc supplied by a rechargeable Li-ion battery pack. The system is designed for medical examination and 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, and optional items. It is intended to be used by a qualified and trained clinician on adult patients. The device is intended to assist the diagnosis of bones and tissues through X-ray exposure using an imaging receptor. The image receptor (an integral part of a complete diagnostic system) is not part of this submission.

7. Indication for use

EzRay M (Model: VMX-P300) is a portable general-purpose X-ray system that users can operate with one hand. The device uses a fixed tube current and voltage (kVp) and, therefore, is limited to taking diagnostic X-rays of extremities. It is intended to be used by a qualified and trained clinician on adult patients. It is not intended to replace a radiographic system with variable tube current and voltage (kVp), which may be required for full optimization of image quality and radiation exposure for different exam types.

8. Substantial Equivalence Chart

		Subject Device	Predicate Device
Device Name		EzRay M (Model: VMX-P300)	NOMAD MD Handheld X-ray System
Applicant Name		VATECH Co., Ltd.	Aribex, Inc.
510(k) Number		K203667	K140723
Device Classification Name		Mobile x-ray system	Mobile x-ray system
Classification Product Code		IZL	IZL
Regulation Number		21 CFR 892.1720	21 CFR 892.1720
Regulation Class		II	II
Indications for Use		EzRay M (Model: VMX-P300) is a portable general-purpose X-ray system that users can operate with one hand. The device uses a fixed tube current and voltage (kVp) and, therefore, is limited to taking diagnostic X-rays of extremities. It is intended to be used by a qualified and trained clinician on adult patients. It is not intended to replace a radiographic system with variable tube current and voltage (kVp), which may be required for full optimization of image quality and radiation exposure for different exam types.	The NOMAD MD is a handheld and portable general purpose X-ray system. The device uses a fixed tube current and voltage (kVp) and, therefore, is limited to taking diagnostic X-rays of extremities. It is intended to be used by a qualified and trained clinician on both adult and pediatric patients. It is not intended to replace a radiographic system with variable tube current and voltage (kVp) which may be required for full optimization of image quality and radiation exposure for different exam types.
Principle of Operation		General Purpose Diagnostic X Ray	General Purpose Diagnostic X Ray
Technological	**Size: Body**	11.0” L x 5.4” W x 11.1” H (excluding Skin Distance Bar)	9.5” H x 5.25” W x 10” L (excluding Source Skin guard)
	Weight	4.14 lbs	11.0 lbs.
	Source to skin distance	30 cm with Skin Distance Bar	30 cm
	Focal Spot	0.5 mm	0.4 mm
	Collimator	Four manually and steplessly adjustable shutters with x-ray field indicator	Four manually and steplessly adjustable shutters with LED Light Field Center Indicator
	User Interface	Jog dial for operating mode selection. Additionally, several user-selectable preset times with exposure time selection icons on a display module.	Up-down buttons for exposure time selection, with timer display.
	Energy source	Rechargeable 21.6 V DC Li-ion polymer battery pack	Rechargeable 14.4 V DC NiCd battery pack
	Exposure time	0.05 - 1.0 seconds in 0.01 increments	0.02 – 0.99 seconds in 0.01 increments
	mA	3.0 mA fixed	2.0 mA fixed
	kVp	65 kVp fixed	75 kVp fixed

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 (K140723) in its indications for use and technological application. Both the subject and predicate devices are taking diagnostic X-rays of extremities using a fixed tube current and voltage (kVp). The exposure parameters of the EzRay M device (KVp, mA, s) are similar to the predicate Nomad MD. For the energy source, battery pack, the subject device receives power from the built-in rechargeable Li-ion polymer battery pack whereas the predicate device (K140723) uses Rechargeable NiCd battery pack. Rechargeable Li-ion polymer 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 62133:2012

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

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 M (Model: VMX-P300) is substantially equivalent to predicate device as described herein.