September 13, 2022

VSI Co., Ltd.
% Mr. Edward Park
CEO
LightenBridge, LLC
4408 Tortuga Lane
McKINNEY TX 75070

Re: K221417
Trade/Device Name: CLAROX plus (Model: VX-100)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: July 12, 2022
Received: August 12, 2022

Dear Mr. Park:

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
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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)*

K221417

Device Name

CLAROX plus (Model: VX-100)

Indications for Use *(Describe)*

CLAROX plus (Model: VX-100) is a portable general-purpose X-ray system that users can operate with one hand. The device uses a fixed X-ray 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 and pediatrics. 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.

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510(k) Summary – Traditional 510(k)

K221417

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information

Submitter Name:	VSI Co., Ltd.
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Contact Person:	Edward Park, official correspondent of AssembleCircle Corp.
Date of submission:	Apr 15, 2022

Device Information

Proprietary Name(s):	CLAROX plus
Model Name:	VX-100
Common Name:	Portable X-ray System
Regulation Name:	Mobile X-ray System
Product Code:	IZL
Regulation Number:	21 CFR 892.1720
Classification Panel:	Radiology
Device Class:	II

Device Description

VX-100 is a battery-operated, portable X-ray source designed for handheld operation. It is designed to produce diagnostic quality X-ray images. The VX-100 is designed for use in general purpose radiography for generating radiographic images of human anatomy, including adult, pediatric, and neonatal exams. Because of its low power output, the Clarox Plus (Model VX-100) is intended for exclusive use on body extremities. The functions of the VX-100 handheld system are supported by software (firmware). The device software is of Moderate level of concern and it is not based on the predicate software. The device uses a rechargeable battery to allow for the use of the VX-100 where transportation or use of other x-ray devices might be prohibitive due to the other device's size and/or lack of mobility. The VX-100 is an X-

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ray device with AC/DC adaptor. The handheld device features a main body (tube head), cone to limit the exposure range of the beam, cradle, and AC/DC adaptor. The power is supplied by a rechargeable Lithium-Ion battery core pack built into a main body. This facilitates portability of the device. A beam-limiting cone is mounted to the device before use. The tube voltage is adjustable from 70kV to 100kV. Tube current is fixed 1.0mA. The exposure time is also manually adjustable by the operators. This adjustment can be quickly accomplished through the user-friendly control panel. Control buttons, display, and an exposure button provide the primary operator interface. Exposures settings can be selected and displayed. The voltage and the exposure time varies based on patient type, detector type, and anatomical feature. Exposures can be completed using the exposure button. The VX-100 should be used with an X-ray detector, and the x-ray detector may be digital or analog, and it is not included in the VX-100 package.

Principle of Operation / Mechanism of Action:

The VX-100 is used like any other Xray source for general radiographic application. An x-ray image receptor (not part of the device) is placed under the body extremity intended for radiography. The appropriate exposure time is manually set by the operator. The operator should follow adequate instructions to ensure proper alignment of the x-ray beam and the image receptor. *To* prevent inadvertent exposure to X-rays, the value adjusted by the MCU electronically controls the semiconductor switching element. Using this X-ray, it passes through the body part to be diagnosed to obtain an image with a detector so that it can be used for diagnosis. The irradiation time setting method sets the irradiation time by the user and can select a value from 0.1 seconds to 1.0 seconds by turning the jog dial manually.

Predicate Device

- EzRay M (Model: VMX-P300) (Vatech Co., Ltd. K203667, February 2, 2021)
  - Common Name: Medical Portable X-ray System
  - Regulation Name: Mobile X-ray System
  - Device Class: II
  - Product Code: IZL
  - Regulation Number: 21 CFR 892.1720
  - Classification Panel: Radiology

Indications for Use

CLAROX plus (Model: VX-100) is a portable general-purpose X-ray system that users can operate with one hand. The device uses a fixed X-ray 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 and pediatrics. 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.

Technological Characteristics

The VX-100 retains same basic design components and operating features as the predicate device, EzRay M (Model: VMX-P300, K203667). The handheld device features a main body, cone, and cradle for charging. The X-ray tube and the battery pack are integrated in the main body. The functionality of the user interface is also similar to the predicate device. Power of the both devices is supplied by a rechargeable Lithium-Ion battery core pack built into a handset. The subject device has 22.2 VDC but VMX-P300 has 21.6 VDC. The battery core packs in both devices are compliant with IEC 62133. Testing has been completed on basic safety and essential performance and the device complies with AAMI ES60601-1; IEC 60601-1-2 (Ed. 4); IEC 60601-1-3, and IEC 60601-2-54.

Device Name	**CLAROX plus (VX-100)**	**EzRay M (Model: VMX-P300)**
510k number	**K221417**	**K203667**
Manufacturer	**VSI Co., Ltd.**	**Vatech Co., Ltd.**
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	CLAROX plus (Model: VX-100) is a portable general-purpose X-ray system that users can operate with one hand. The device uses a fixed X-ray 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 and pediatrics. 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.	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.

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Device Name	CLAROX plus (VX-100)	EzRay M (Model: VMX-P300)
510k number	**K221417**	**K203667**
Manufacturer	**VSI Co., Ltd.**	**Vatech Co., Ltd.**
Principle of Operation	General Purpose Diagnostic X-Ray	General Purpose Diagnostic X-Ray
Body Size	413mm(W) × 144mm(D) × 284mm(H)	279.4mm(L) × 137.2mm(W) × 282mm(H)
Weight	2.5kg	1.88kg
Source to image receptor distance	650mm	
Focal Spot	0.6 mm (complied with IEC 60336)	0.5mm
Collimator		Four manually and steplessly adjustable shutters with x-ray field indicator
User Interface	Jog dial for operating mode selection, control panel, control buttons (icons), display, and an exposure button	Jog dial for operating mode selection, display module, and exposure icons on it.
Energy Source	Rechargeable 22.2 V DC Li-ion polymer battery core pack	Rechargeable 21.6 V DC Li-ion polymer battery core pack
Battery Capacity	1.46 A-hr	
Recharge capability	80% or above remaining capacity after 300 cycles	
Exposure time	0.1 – 1.0 seconds 0.2 in 0.02 sec increments	0.05 – 1.0 seconds in 0.01 sec increments
Timer Accuracy	± (10 % + 1 ms)	
mA	1.0 mA	3.0 mA
kVp	70 kV – 100 kV (5kV step)	65 kVp fixed
Waveform	Constant Potential (DC)	Constant Potential (DC)

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Performance Data

Non-clinical test was performed in accordance with the following international standards,

- ANSI AAMI IEC 62304:2006 Medical Device Software – Software Life Cycle Processes
- EN ISO 14971:2019 Medical devices - Applications of risk management to medical devices
- ANSI AAMI IEC 62366-1:2015+AMD1:2020 Medical devices Part 1: Application of usability engineering to medical devices
- AAMI ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment – Part 1; General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)
- EN 60601-1-2:2015, Electromagnetic Compatibility (EMC) Testing for Medical Devices including the NEW IEC 60601-1-2 4th Edition
- IEC 60601-1-3 Edition 2.1 2013-04 Medical Electrical Equipment – Part 1-3: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Radiation Protection in Diagnostic X-ray Equipment
- IEC 60601-1-6 Edition 3.1 2013-10 Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
- IEC 60601-2-28 Edition 3.0 2017-06 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- IEC 60601-2-54 Edition 1.2 2018-06 Medical Electrical Equipment - Part 2-54: Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment For Radiography And Radioscopy
- IEC/EN 62133-2 Edition1.0 2017-02 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 - Part 2: Lithium systems

Clinical testing was not necessary for the VX-100, based on the nature of the device (an x-ray generator marketed without image detector). Adequate bench testing results should be sufficient in supporting our claim of substantial equivalence.

Conclusion

The subject device is substantially equivalent in the areas of indications for use, general functions & features, principle of operation, and technological characteristics. The new device does not introduce a fundamentally new scientific technology. Therefore, we conclude that the subject device described in this submission is substantially equivalent to the predicate device.