June 29, 2022

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

Re: K221286
Trade/Device Name: CLAROX
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: May 3, 2022
Received: May 3, 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)*
K221286

Device Name
CLAROX

Indications for Use *(Describe)*
The CLAROX is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral 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.

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510(k) Summary – Traditional 510(k)

K221286

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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Phone/Fax	+82-43-267-9039 / +82-43-269-4039
Contact Person:	Edward Park, official correspondent of AssembleCircle Corp.
Date of submission:	Apr 15, 2022

Device Information

Proprietary Name(s):	CLAROX
Model Name:	VX-30
Common Name:	Portable X-ray Equipment
Regulation Name:	Extraoral Source X-Ray System
Product Code:	EHD
Regulation Number:	21 CFR 872.1800
Classification Panel:	Radiology
Device Class:	II

Device Description

CLAROX is a battery-operated, portable dental X-ray source designed for handheld operation. It is designed to produce diagnostic quality X-ray images. The CLAROX is designed for use in a dental office. It can also be used in other similar environments (orthodontic office, general practitioner's office, hospital ward, etc.) where appropriate safeguards are implemented. The device uses a rechargeable battery to allow for the use of the CLAROX 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 CLAROX is an X-ray device with a AC/DC adaptor. The handheld device features a main body (tube head), Cone for sensor, Acryl shielding, 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 incorporated within the device. The acryl shielding provide sufficient radiation protection to allow the clinician to remain in the operatory with the patient. To make the system as simple as possible for the operator, CLAROX uses a fixed tube voltage of 70kV and a fixed tube current of 2.0 mA. The only operator-adjustable parameter is the exposure time. 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. Voltage (70 kV) and current (2.0 mA) are fixed with the exposure time varying based on patient type, detector type, and anatomical feature. Exposures can be completed using the exposure button. The CLAROX should be used with an X-ray detector, and this detector has digital type and analog film type. But the X-ray detector is not included in the device package. The functions of the CLAROX x-ray system are controlled by software (firmware). The device software is not based on the predicate and it is of Moderate level of concern.

Principle of Operation / Mechanism of Action:

The CLAROX is used like any other extraoral dental Xray source for intraoral application. An image receptor, such as film, is placed in the patient's oral cavity behind the teeth. The device is powered on, and the appropriate exposure time is set by the operator. The operator should follow appropriate instructions to ensure proper alignment of the X-ray beam to the receptor, and proper positioning of a detector in the patient's mouth. The irradiation time is set manually. 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 0.12 seconds to 1.2 seconds by turning the dial manually. After setting, press the investigation button to perform investigation. The system has numerous beep sound alerts to communicate with the operator.

Predicate Device

- KaVo NOMAD Pro2 Handheld X-ray System (Aribex K173319, 10/20/2017)

  - Common Name: Extraoral Source X-ray System
  - Regulation Name: Extraoral Source X-Ray System
  - Device Class: II:
  - Product Code: EHD
  - Regulation Number: 21 CFR 872.1800
  - Classification Panel: Radiology

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Indications for Use

The CLAROX is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.

Technological Characteristics

The CLAROX retains the same basic design components and operating features as the predicate device, KaVo NOMAD Pro 2 Handheld X-ray System (K173319). The handheld device features a main body, Acryl shielding, and cradle for charging. The X-ray tube (70 kV, 2.0 mA) and battery pack are integrated in the main body. The functionality of the user interface is also similar to the previous product, including the pre-programmed exposure times for adult and pediatric patients. The power is supplied by a rechargeable Lithium-Ion battery core pack built into a handset. Both devices have 22.2 VDC but CLAROX has lower battery capacity, but recharge capacity of the subject device is better than the predicate device. The design of the subject device also looks similar to the predicate device. 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 60601-2-65.

Device Name	**CLAROX**	**KaVo NOMAD Pro2 Handheld X-ray System**
510k number		**K173319**
Manufacturer	**VSI Co., Ltd.**	Aribex
Indications for Use	The CLAROX is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce E-ray images using intraoral image receptors.	The KaVo NOMAD Pro 2 Handheld X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.
Body Size	300mm(W) × 100mm(D) × 252mm(H)	279mm(L) × 140mm(W) × 267mm(H)
Weight	1.5kg	2.73kg
Source to skin distance	200mm	210mm
Cone diameter	60mm	60mm

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Device Name	**CLAROX**	**KaVo NOMAD Pro2 Handheld X-ray System**
510k number		**K173319**
Manufacturer	**VSI Co., Ltd.**	Aribex
User Interface	control panel. control buttons, display, and an exposure button	Control buttons, display, and a trigger
Energy Source	Rechargeable 22.2 V DC Li-polymer battery core pack	Rechargeable 22.2 V DC Li-polymer battery core pack
Battery Capacity	1.46 A-hr	1.7 A-hr
Recharge capability	80% or above remaining capacity after 300 cycles	70% remaining capacity after 300 cycles
Exposure time	0.12 – 1.2 seconds in	0.02 – 1.0 seconds
Timer Accuracy	Less than 5% or 20 ms	±(10% + 1ms)
mA	2.0 mA	2.5 mA
kVp	70 kVp	60 kVp
Waveform	Constant Potential (DC)	Constant Potential (DC)

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)
- 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 60601-1-2 Edition 4.0 2014-02 Medical Electrical Equipment – Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements And Tests
- 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
- IEC 60601-2-65 Edition 1.0 2012-09 Medical Electrical Equipment – Part 2-65: Particular Requirements for the Basic Safety And Essential Performance of Dental Intra-Oral X-Ray Equipment

Complete device testing has been performed for the CLAROX handheld x-ray system and successful test results indicate device safety and effectiveness.

Clinical testing is not necessary for the current submission, based on the device type (an x-ray generator) and based on the technological characteristics similar to the predicate system. Successful results of bench testing should be sufficient evidence 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.