November 23, 2022

Guilin Woodpecker Medical Instrument Co., Ltd.
% Charles Mack
Principal Engineer
IRC
2950 E Lindrick Drive
CHANDLER, AZ 85249

Re: K222569
Trade/Device Name: Ai Ray Dental X-Ray Device
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: EHD
Dated: August 24, 2022
Received: August 24, 2022

Dear Charles Mack:

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,

Lu Jiang
2022.11.23
09:33:38 -05'00'

Lu Jiang, 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)*

K222569

Device Name

Ai Ray Dental X-Ray Device

Indications for Use *(Describe)*

Ai Ray Dental X-Ray Device 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.

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K222569 510(k) SUMMARY

Preparation Date:	November 21, 2022
Manufacturer's Name and Address:	Guilin Woodpecker Medical Instrument Co., Ltd Information Industrial Park, Guilin National High-Tech Zone, Guilin City, Guangxi Province, China 541004
Corresponding Official:	Charles Mack
Telephone Number:	931-625-4938
Email Address:	charliemack@irc-us.com
Trade Name:	Ai Ray Dental X-Ray Device
Common Name(s):	unit, x-ray, extraoral with timer,
Regulation Name(s):	Extraoral source x-ray system
Regulation Number(s):	21CFR872.1800
Product Code:	EHD
Device Class:	Class II
Predicate Device:	Vatech Co., Ltd K200182
Trade Name:	EzRay Air Portable (Model: VEX-P300)
Common Name(s):	unit, x-ray, extraoral with timer,
Regulation Name(s):	Extraoral source x-ray system
Regulation Number(s):	21CFR872.1800
Product Code:	EHD
Device Class:	Class II

Device Description:

Ai Ray Dental X-Ray Device is a super capacitor-operated, portable dental X-ray source designed for handheld operation. It is designed to produce diagnostic quality X-rays images utilizing either film or digital imaging techniques. The Portable Dental X-ray Device 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 supercapacitor to allow for the use of the Portable Dental X-ray Device 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 proposed Ai Ray Dental X-Ray Device is similar in design to the predicate EzRay Air Portable, VEX-P300 (K200182). The proposed Ai Ray Dental X-Ray Device and the predicates is a portable dental X-ray system intended for use by a trained and qualified dentist or dental technician for both adult and pediatric subjects for producing diagnostic dental radiographs for treatment of diseases of the teeth, jaw, and other oral structures using intra-oral image receptors.

The differences between the proposed Ai Ray Dental X-Ray Device and the predicate EzRay Air Portable, VEX-P300 (K200182) are as follows：

1. The opening key is positioned differently, EzRay Air Portable at the bottom and Ai Ray at the top.
2. The structural shapes of the two devices are different.

Principles of Operation

The equipment acquires images by emitting X-rays continuously on a human tooth. X-rays are emitted when high voltage is supplied to the X-ray tube assembly, which frees electrons from the cathode. They hit the anode to produce X-rays.

Comparison of Technological Characteristics with the Predicate Device

Characteristics	Subject Device	Predicate Device	Discussion
Device	Ai Ray Dental X-Ray Device	EzRay Air Portable (Model: VEX-P300)	-
510K Applicant	Guilin Woodpecker Medical Instrument Co., Ltd.	Vatech Co., Ltd	-
510(K) Number	Pending	K200182	-
Regulation Number	CFR872.1800	CFR872.1800	Identical
Product Code	EHD	EHD	Identical
Classification Name	Extraoral source x-ray system	Extraoral source x-ray system	Identical
OTC or Prescription	Prescription Use	Prescription Use	Identical
Medical Specialty	Dental	Dental	Identical
Indication for Use	Ai Ray Dental X-Ray Device 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.	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.	Identical
Principle of Use	X-ray tube	X-ray tube	Identical
Mechanical			
Size (L x W x H)	114mm×363.8mm×245.6mm	280 x 165 x 296 mm	Different. Note 1
Source to Skin Distance	200~230mm	200 mm	Different. Note 2
X-ray Field Size	Φ5.6cm±0.1cm	6cm round	Different. Note 3

Mechanical			
Characteristics	**Subject Device**	**Predicate Device**	**Discussion**
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.	Identical
Backscatter Radiation Protection	162 mm dia., Pb-filled acrylic plastic, Back Scattering shield	165 mm dia., Pb-filled acrylic plastic, Back Scattering shield	Different. Note 4
Exposure Switch	Exposure button on the handset	Exposure button on the handset	Identical
Tube Head Mounting	Handheld	Handheld	Identical
Electrical			
Energy Source	Rechargeable 10.8V DC Li-ion polymer battery pack (Nominal Capacity: 2450~2500mAh)	Rechargeable 21.6 V DC Li-ion polymer battery pack (Nominal Capacity: 2,500 mAh)	Different. Note 5
Exposure Time	0.04-1.0 seconds in 0.01 increments	0.05 - 1.0 seconds in 0.01 increments	Different. Note 6
Tube Current (mA)	3 mA fixed, error±20%	2.5 mA fixed	Different. Note 7
Tube Voltage (kVp)	70 kV fixed, error±10%	60 or 65 kV fixed	Different. Note 8
Waveform	Constant Potential (DC)	Constant Potential (DC)	Identical
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 CFR1020.30, 1020.31	Identical

Differences Discussion:

Note1 The physical shape/size difference has no impact on safety and performance. Both devices conform to the same safety and performance standards.

Note 2 The distance difference has no impact on safety and performance.
Both devices conform to the same safety and performance standards.

Note 3 The difference has no impact on safety and performance. Both devices conform to the same safety and performance standards.

Note 4 The size of the backscattering shield is different due to different device shapes.
The radiation leakage value of the device with a backscattering shield after testing meets the requirements of the FDA. Security and performance are not affected.

Note 5 Although the battery specifications are different, they conform to the same requirement of IEC 62133 for the rechargeable battery. The differences do not raise issues of safety and effectiveness.

Note 6 Both devices conform to the same requirement of federal standard requirements. The performance test demonstrated that the difference doesn't raise safety and effectiveness issues.

Note 7 Although the X-ray tube's specifications are not identical and conform to the same performance standards IEC 60601-2-65, The performance test demonstrated the difference doesn't raise safety and effectiveness issues.

Note 8 Although the X-ray tube's specifications are not identical, and they conform to the same performance standards IEC 60601-2-65. The performance test demonstrated that the difference doesn't raise safety and effectiveness issues.

Performance Testing

Performance testing was provided to support the substantial equivalence determination and to validate and verify that the Ai Ray Dental X-Ray Device met all requirements of related applicable standards. The results of these tests demonstrate compliance with the requirements of the consensus standards noted below.

Non-Clinical Performance Testing

Non-clinical performance testing was performed to verify substantial equivalence to predicate devices.

Safety and EMC:

- ANSI AAMI ES60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances – Requirements and tests

Performance:

- 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
- IEC 60601-2-65 Edition 1.1 2021-05 CONSOLIDATED VERSION Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral-X-ray equipment
- IEC 61223-3-4 First edition 2000-03 Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray
- IEC 62304:2006/A1:2015 “Medical device software – Software life cycle processes.”

- IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- FDA Guidance for Radiation Safety Considerations for X-Ray Equipment Designed for Handheld Use
- FDA Guidance: “Pediatric Information for X-ray Imaging Device Premarket Notifications,” dated November 28, 2017
- 21 CFR 1020.30 Diagnostic x-ray system and their major components
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Clinical Performance Data

No clinical data was required to demonstrate substantial equivalence.

Conclusions:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Ai Ray Dental X-Ray Device is substantially equivalent to the Vatech Co., Ltd, Inc. EzRay Air Portable (Model: VEX-P300) cleared under K200182 with respect to the indications for use, target populations, treatment method, and technological characteristics.

-END-