March 12, 2026

Guangzhou Ajax Medical Equipment Co., Ltd.
℅ Jett Lee
Regulation Manager
SGS-CSTC Standards Technical Services Co., Ltd
198 KEZHU Road, SCIENTECH Park Guangzhou Economic &
Technology Development District, Tianhe district
GUANGZHOU, GUANGDONG 510000
CHINA

Re: K252110
Trade/Device Name: Dental X-RAY Unit (AJX200)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: EHD
Dated: February 2, 2026
Received: February 2, 2026

Dear Jett Lee:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252110

Please provide the device trade name(s).

Dental X-RAY Unit (AJX200)

Please provide your Indications for Use below.

The Unit is an extraoral source dental radiographic x-ray unit. This unit works as diagnostic purpose x-ray source for human teeth with resultant image recorded on intraoral dental x-ray film or image receptor. The unit is intended to be used in a dental hospital or general hospital with a dental office and should have a separate space to install and use this product. The device is intended to be used for adult and pediatric patients.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Date of the summary prepared: November 9, 2025

510(k) Summary： K252110

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92. This is a traditional 510(K) submission with no previous application.

1. Submitter's and Subject Device Information

Sponsor

- Company Name: Guangzhou Ajax Medical Equipment Co., Ltd.
- Address: Building No.2, Dagang Industrial Zone, Shilou Town, Panyu District, Guangzhou City, Guangdong Province, 511447, P.R. China
- Phone: +8618776169232
- Contact Person (including title): Sophia Xu (Registered Engineer)
- E-mail: xuefang.xu@ajaxdent.cn

Application Correspondent

- Company Name: Guangzhou Ajax Medical Equipment Co., Ltd.
- Address: Building No.2, Dagang Industrial Zone, Shilou Town, Panyu District, Guangzhou City, Guangdong Province, 511447, P.R. China
- Tel: 86-13512755282
- Contact Person: Jett Lee
- Email: jianda-lee@foxmail.com

Subject Device Information

- Type of 510(k) submission: Traditional
- Common Name: Unit, X-Ray, Extraoral With Timer
- Trade Name: Dental X-RAY Unit (AJX200)
- Model: AJX200
- Classification Name: Extraoral source x-ray system
- Review Panel: Radiology
- Product Code: EHD
- Regulation Number: 21 CFR 872.1800
- Regulation Class: II

2. Predicate Device Information

	Predicate Device
Sponsor	Vatech Co., Ltd
Device Name	EzRay Air Portable
Model	VEX-P300

510(k) Number	K200182
Product Code	EHD
Regulation Number	21 CFR 872.1800
Regulation Class	II

3. Product Description

3.1 Description of the device and its operating principle

3.1.1 Working Principle

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.

3.1.2 Indication for Use

The Unit is an extraoral source dental radiographic x-ray unit. This unit works as diagnostic purpose x-ray source for human teeth with resultant image recorded on intraoral dental x-ray film or image receptor. The unit is intended to be used in a dental hospital or general hospital with a dental office and should have a separate space to install and use this product. The device is intended to be used for adult and pediatric patients.

3.1.3 Use Environment

To ensure proper function and prevent damage, Ajax equipment should be stored, transported, and operated within the following temperature, humidity, and air pressure ranges:

Temperature/Humidity/Air Pressure	Specifications
Storage/Transportation	● Temperature: -4° F to 131° F (-20° C to 55° C) ● Relative Humidity: 5% to 95% ● Air Pressure: 700hPa to 1060hPa
Operation	● Room Ambient Temperature: 40°F to 104°F (4°C to 40°C) ● Relative Humidity: 20% to 80% ● Air Pressure: 700hPa to 1060hPa

4. Substantial Equivalence Discussion

Elements of Comparison	**Subject Device**	**Predicate Device**	**Comparison**
Trade Name	Dental X-RAY Unit (AJX200)	EzRay Air Portable (Model: VEX-P300)	-
Submitter	Guangzhou Ajax Medical Equipment Co., Ltd.	Vatech Co., Ltd	-
Product Code	Applying	K200182	-
Regulation Number	CFR872.1800	CFR872.1800	-
Product Code	EHD	EHD	-
Prescription / Over - The - Counter Use	Prescription Use	Prescription Use	-

Medical Specialty	Dental	Dental	-
Intended Use	The Unit is an extraoral source dental radiographic x-ray unit. This unit works as diagnostic purpose x-ray source for human teeth with resultant image recorded on intraoral dental x-ray film or image receptor. The unit is intended to be used in a dental hospital or general hospital with a dental office and should have a separate space to install and use this product. The device is intended to be used for 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.	SE
Principle of Use	X-ray tube	X-ray tube	SE
Source to Skin Distance	200mm	200 mm	SE
X-ray Field Size	58mm dia., circular	6cm round	SE
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.	Same
Exposure Switch	Exposure switch on the handset	Exposure button on the handset	SE
Tube Head Mounting	Wall mounted	Handheld	SE Note 1
Energy Source	Single-phase AC 100-240V, ±10%	Rechargeable 21.6 V DC Li-ion polymer battery pack (Nominal Capacity: 2,500 mAh)	SE Note 2
Exposure Time	0.02~2.00s, regulated according to the R10 coefficient	0.05 - 1.0 seconds in 0.01 increments	SE Note 3
Tube Current (mA)	2.5mA	2.5 mA fixed	SE
Tube Voltage (kVp)	65kV	60 or 65 kV fixed	SE
Waveform	Constant Potential (DC)	Constant Potential (DC)	SE
Applied Standard	IEC 60601-1, IEC 60601-1-3, IEC 60601-2-65, IEC 60601-1-6, IEC 60601-2-28	IEC 60601-1, IEC 60601-1-3, IEC 60601-2-65, IEC 60601-1-2, 21 CFR1020.30, 1020.31	SE

Comparison in Detail(s):

Note 1(Tube Head Mounting):

The subject device is a wired digital detector, while the predict device is portable. These minor differences are related to the product design of each manufacturer, but do not affect its function. And the subject device comply with IEC 60601-1 and will not raise any safety or effectiveness issue.

Note 2(Energy Source):

The AC energy source of subject device will be converted to DC by main control board. And the subject device comply with IEC 60601-1 and will not raise any safety or effectiveness issue.

Note 3(Exposure Time):

The exposure time is adjustable to the optimum value according to the tooth type. These minor differences do not affect its function. And the subject device comply with IEC 60601-1 and will not raise any safety or effectiveness issue.

5 Performance Data:

The following performance data were provided in support of the substantial equivalence determination.

1)Electrical safety and electromagnetic compatibility

The test results demonstrated that the proposed device complies with the following standards:
IEC 60601-1:2005 A1: 2012+A2: 2020 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-3:2008+AMD1:2013+AMD2:2021 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-28:2017 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis.
IEC 60601-2-65:2012+AMD1:2017+AMD2:2021 Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment.
IEC 60601-1-2:2014 A1:2020 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

2)Software verification and validation testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's 2023 Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions". The software for this device was developed and reviewed under an Enhanced Documentation Level.

3)Bench Testing

The performance test had been conducted to verify the X ray module voltage and current accuracy, loading accuracy, accuracy of loading factor and imaging performance testing.
The service lifetime of had been conducted, it is verified that the exposure life of the wall-mounted dental X-ray device reach 10000 times.

6 Comparison to predicate device and conclusion

The Intended Use, Principle of Use, Source to Skin Distance, X-ray Field Size, Tube Current and Tube Voltage of Dental X-RAY Unit, model: AJX200 is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate device do not raise new issues of safety or effectiveness.