September 4, 2025

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

Re: K251438
Trade/Device Name: Dental X-Ray Device (Ai Ray Lite, Ai Ray Pro, Master Ray )
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: EHD
Dated: May 7, 2025
Received: August 12, 2025

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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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 Radiologic 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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K251438

Device Name
Dental X-Ray Device (Ai Ray Lite, Ai Ray Pro, Master Ray )

Indications for Use *(Describe)*
Dental X-Ray Device, Ai Ray Lite, Ai Ray Pro, Master Ray
It 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) SUMMARY

| | |
|---|---|
| Preparation Date: | May 7, 2025 |
| | |
| Manufacturer's Name and Address: | Guilin Woodpecker Medical Instrument Co., Ltd.<br>Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, China 541004 |
| | |
| Corresponding Official: | Charles Mack |
| | |
| Telephone Number: | 931-625-4938 |
| | |
| Email Address: | charliemack@irc-us.com |
| | |
| Trade Name: | Dental X-Ray Device (Ai Ray Lite, Ai Ray Pro, Master Ray) |
| | |
| Common Name(s): | unit, x-ray, extraoral with timer |
| | |
| Regulation Name(s): | Extraoral source x-ray system. |
| | |
| Regulation Number(s): | 21CFR872.1800 |
| | |
| Primary Product Code:<br>Subsequent Product Codes: | EHD |
| | |
| Device Class: | Class II |
| | |
| Predicate Device: | K222569 |
| Trade Name: | Ai Ray Dental X-Ray Device |
| Common Name: | Extraoral source x-ray system |
| Regulation Number(s): | 21CFR872.1800 |
| Product Code: | EHD |
| Subsequent Product Codes: | |

## Device Description:

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-ray images utilizing either film or digital imaging techniques. The Portable Dental X-ray Device is intended 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 super capacitor to allow for 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 subject devices are the same as our previously cleared AI Ray (Predicate-K222569) in indication for use, fundamental scientific technology, operating parameters, etc. The design changes are only related to several physical specifications (shape, size, weight, shell color) and several performance specifications.

All these changes are verified and validated according to the well-established method in the applicable standards, as defined below. The test result shows the subject devices are as safe and effective as and substantially equivalent to the predicate devices described herein.

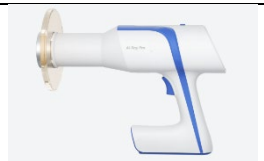
- Electric Safety and EMC
- Performance
- Software Validation

**Indications for Use**

Dental X-Ray Device, Ai Ray Lite, Ai Ray Pro, Master Ray

It 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.

# Comparison to Predicate Device

| Characteristics | Predicate Device | Subject Device | Subject Device | Subject Device | Discussion |
|---|---|---|---|---|---|
| Device | Ai Ray | Ai Ray Pro | Ai Ray Lite | Master Ray | - |
| 510K Applicant | Guilin Woodpecker Medical Instrument Co., Ltd. | Guilin Woodpecker Medical Instrument Co., Ltd. | Guilin Woodpecker Medical Instrument Co., Ltd. | Guilin Woodpecker Medical Instrument Co., Ltd. | Identical |
| 510(K) Number | K222569 | Pending | Pending | Pending | - |
| Regulation Number | CFR872.1800 | CFR872.1800 | CFR872.1800 | CFR872.1800 | Identical |
| Product Code | EHD | EHD | EHD | EHD | Identical |
| Classification Name | Extraoral source x-ray system | Extraoral source x-ray system | Extraoral source x-ray system | Extraoral source x-ray system | Identical |
| OTC or Prescription | Prescription Use | Prescription Use | Prescription Use | Prescription Use | Identical |
| Medical Specialty | Dental | Dental | Dental | Dental | Identical |
| Indication for Use | It is an extraoral diagnostic dental X-ray source that produces X-ray images using intraoral image receptors. It is indicated for use by a dentist or a dental technician on adult and pediatric patients. | It 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. | It 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. | It 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 |
| Product Appearance |  |  |  |  | *Note 1* |
| Principle of Use | X-ray tube | X-ray tube | X-ray tube | X-ray tube | Identical |
| Size (L x W x H) | 363.8mm x114mm x 245.6mm | 363.8mm x114mm x 245.6mm | 338mm×112mm×247mm | 240mm×161mm×143mm | *Note 2* |
| Source to Skin Distance | 200~230mm | 200~230mm | 200~230mm | 200~230mm | Identical |
| X-ray Field Size | Φ5.9cm±0.1cm | Φ5.9cm±0.1cm | Φ5.9cm±0.1cm | Φ5.9cm±0.1cm | Identical |
| Backscatter Radiation Protection | 162 mm dia., Pb-filled acrylic plastic, Back Scattering shield | 162 mm dia., Pb-filled acrylic plastic, Back Scattering shield | 162 mm dia., Pb-filled acrylic plastic, Back Scattering shield | 162 mm dia., Pb-filled acrylic plastic, Back Scattering shield | Identical |

| Characteristics | Predicate Device | Subject Device | Subject Device | Subject Device | Discussion |
|---|---|---|---|---|---|
| Device | Ai Ray | Ai Ray Pro | Ai Ray Lite | Master Ray | - |
| Exposure Switch | Exposure button on the handset | Exposure button on the handset | Exposure button on the handset | Exposure button on the handset | Identical |
| Tube Head Mounting | Handheld | Handheld | Handheld | Handheld | Identical |
| Energy Source | Rechargeable 10.8V DC Li-ion polymer battery pack: 2500mAh*3*2 | Rechargeable 10.8V DC Li-ion polymer battery pack: 2500mAh*3*2 | Rechargeable 10.8V DC Li-ion polymer battery pack: 2500mAh*3*1 | Rechargeable 10.8V DC Li-ion polymer battery pack: 2500mAh*3*1 | *Note 3* |
| Exposure Time | 0.04-1.0 seconds in 0.01 increments | 0.04-1.0 seconds in 0.01 increments | 0.02-2.0 seconds in 0.01 increments | 0.02-2.0 seconds in 0.01 increments | *Note 4* |
| Tube Current | 3 mA fixed , error±20% | 3 mA fixed , error±20% | 2 mA fixed ,error±20% | 2 mA fixed ,error±20% | *Note 5* |
| Tube Voltage (kVp) | 70 kV fixed, error±10% | 70 kV fixed, error±10% | 70 kV fixed, error±10% | 70 kV fixed, error±10% | Identical |
| Output power | 210W | 210W | 140W | 140W | *Note 5* |
| Power adapter | Input: 100~240V～ 50/60Hz, 1.5A Output:15.0V 5.67A | Input: 100~240V～ 50/60Hz, 1.5A Output:15.0V 5.67A | Input: 100~240V～ 50/60Hz, 0.8A Output:15.0V 1.6A | Input: 100~240V～ 50/60Hz, 1.1A Output:15.0V 3.2A | *Note 6* |
| Waveform | Constant Potential (DC) | Constant Potential (DC) | 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 CFR 1020.30, 1020.31 | 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 CFR 1020.30, 1020.31 | Identical |

**Discussion:**

***Note 1***

The Ai Ray and Ai Ray Pro differ only in the model number and color of the decorative strips on the housing; they are completely identical in other aspects.

Ai Ray Lite has the same shape as Ai Ray but is smaller and lighter; they are completely identical in other aspects.

Master Ray has a camera-like shape. Although the external appearance differs, the internal circuit design and the control method are the same.

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

***Note 2***

For physical size, Ai Ray Pro is the same as the predicate device; Ai Ray Lite is a scaled-down version of the predicate device; and Master Ray is different from the predicate device. The physical shape/size difference has no impact on safety and performance. Both devices conform to the same safety and performance standards.

***Note 3***

The Ai Ray Lite and Master Ray have only 1 set of batteries, the batteries conform to the same IEC62133 requirement as the predicate device; The quantity of batteries doesn't raise issues of safety and effectiveness.

***Note 4***

Ai Ray Lite and Master Ray's exposure time is different from that of the predicate device. However, the time of each preset gear is the same as that of the predicate device; that is, the exposure time in the same mode is the same. The user-adjustable time range is wider. They conform to the same federal standard requirements. The performance test demonstrated that the difference doesn't raise safety and effectiveness issues.

***Note 5***

The Ai Ray Lite and Master Ray's tube current and output power are different from those of the predicate device, but 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.

***Note 6***

The difference only affects the charging speed, but 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**

We performed the tests noted below on the subject devices to establish substantial equivalence to the identified predicate devices. The testing results proved that the device complies with the applicable standards requirement and is substantially equivalent to the predicate devices.

**Non-Clinical Performance Testing**

Testing was performed to evaluate the functional performance and safety of the subject device with the following standards:

**Safety and EMC:**

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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
- ISO 14971 Third Edition 2019-12 Medical devices- Application of risk management to medical devices
- FDA Guidance-Content of Premarket Submissions for Device Software Functions

**Performance:**

- IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic 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 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
- FDA Guidance Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use

**Conclusions:**

Based on the verification test results, the subject devices, Dental X-Ray Device, Ai Ray Lite, Ai Ray Pro, and Master Ray, conform to the same standards requirements, such as performance, safety, EMC, and software as the predicate device. These address the changes made in the predicate device. The subject device uses the same fundamental scientific technology and indications for use and functionality. The differences do not raise new questions about the safety and effectiveness of the proposed device.

**END**