February 19, 2026

Guilin Refine Medical Instrument Co., Ltd.
% Ms. Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
SAINT PAUL, MN 55114

Re: K254018
Trade/Device Name: Portable Dental X-ray Device (GT-1)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: October 28, 2025
Received: February 2, 2026

Dear Prithul Bom:

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.	K254018

Please provide the device trade name(s).

Portable Dental X-ray Device (GT-1)

Please provide your Indications for Use below.

The Portable Dental X-ray Device is intended to be used by dental professionals to provide an extraoral X-ray source to produce radiographic images of the teeth using intraoral image receptors for clinical diagnostic purposes.

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)

510(K) SUMMARY
K254018

I. 807.92(a)(1): SUBMITTER

Company Name: Guilin Refine Medical Instrument Co., Ltd.
Address: No 8-3, Information Industrial Park, High-Tech Zone, Qixing District, Guilin, Guangxi, 541004 CHINA
Contact: Su Qin
Phone: (+86) 18074840560
Email: register@refine-med.com
Date the summary was prepared: February 17, 2026

II. 807.92(a)(2): DEVICE

Device Name: Portable Dental X-ray Device (GT-1)
Regulation Description: Extraoral source x-ray system
Regulation Number: 21 CFR §872.1800
Product Code: EHD
Classification: Class II

III. 807.92(a)(3): PREDICATE DEVICE

Predicate Device: K232068
Device Name: HyperLight Portable X-ray Unit
Regulation Description: Extraoral source x-ray system
Regulation Number: 21 CFR §872.1800
Product Code: EHD
Classification: Class II

IV. 807.92(a)(4) DEVICE DESCRIPTION

The Portable Dental X-ray Device is intended to be used by dental professionals to provide an extraoral X-ray source to produce radiographic images of the teeth using intraoral image receptors for clinical diagnostic purposes.

The high voltage generator provides high voltage to both ends of the X-ray tube filament and metal target in the internal X-ray source assembly, a large number of electrons are generated on the cathode filament of the X-ray tube and move at a high speed in the vacuum tube, impacting the metal target to generate the X-ray. The X-ray penetrate the different tissue densities of the body, such as teeth and muscles after passing through the X-ray window and beam tube, the X-ray which carry image information through body tissue, are passed through image receiving devices such as phosphor sheets, film or digital image receivers, to show different densities of human tissue images. The image receptors (necessary accessory for a fully functional intra-oral system) are not part of the subject device.

The product is a high frequency dental X-ray equipment, rated tube voltage is 65kV DC, rate tube current is 2.5 mA, the inverter X-ray control method is adopted, for chemical film and digital sensor diagnostics to obtain high quality dental images, the power supply of GT-1 is 14.4V DC, powered by a rechargeable battery pack.

The USB type-C port is a power-only port, and its data line function is disabled.

The equipment is only for qualified professional technicians and trained or qualified professionals (such as a dentist) in the hospital or clinic to use. The equipment belongs to the radioactive equipment, the operator should operate the equipment according to the users, manual, the equipment shall not be used for other purposes except for medical radiography.

V. 807.92(a)(5): INTENDED USE/INDICATIONS FOR USE

The Portable Dental X-ray Device is intended to be used by dental professionals to provide an extraoral X-ray source to produce radiographic images of the teeth using intraoral image receptors for clinical diagnostic purposes.

VI. 807.92(a)(6): SUBSTANTIAL EQUIVALENCE COMPARISON

Comparison of the Intended Use/Indications for Use

Subject Device: The Portable Dental X-ray Device is intended to be used by dental professionals to provide an extraoral X-ray source to produce radiographic images of the teeth using intraoral receptors for clinical diagnostic purposes.

Predicate Device: The device is a diagnostic X-ray system which is intended to be used by trained dentists and dental technicians as an extra-oral X-ray source for producing diagnostic x-ray images using intra-oral receptors. Its use is intended for both adults and

pediatric subjects.
(Same)

<Physical Characteristics>

Size (The dimension is with the mandatory beam limiting device.) Subject
Device: 13.9” x 4.58” x 10.5”
Predicate: 11.85” x 4.58” x 9.97”
(Difference of design, size. This does not affect the safety and effectiveness of the medical device.)

Source to Skin Distance
Subject Device: 21.4cm
Predicate: 20 cm
(Difference 1.4 cm. IEC 60601-2-65 requires that the source-to-skin distance be greater than 20 cm. The subject device is designed with a longer source-to-skin distance; as a result, the divergence angle of the X-ray beam is smaller, and the radiation is more concentrated, which can reduce scattered radiation to non-examined areas of the patient.)

Cone diameter Subject
Device: 5.4cm
Predicate: 5.7 cm
(Difference 0.3 cm. IEC 60601-2-65 requires that the cone diameter be less than 6 cm. The subject device features a smaller cone diameter, which reduces the generation of scattered radiation, minimizes artifacts, and lowers the patient's surface dose.)

User interface
Subject Device: Up-down buttons for exposure time selection. Additionally, several user-selectable preset times with patient size, image-receptor type, and tooth selection icons on an LCD display.
Predicate: Up-down buttons for exposure time selection with timer display. Additionally, several user-selectable preset times with patient size, and tooth selection icons on an LCD display.
(Same)

Backscatter radiation protection
Subject Device: 154.5mm dia.8mm thick Pb-filled acrylic plastic scatter shield Predicate: 159.5mm dia.13mm thick Pb-filled acrylic plastic scatter shield
(5mm difference in diameter and 5mm difference in thickness. This does not affect the safety and effectiveness of the medical device.)

Exposure switch
Subject Device: Exposure trigger at the lower front area of the main body or external exposure switch.
Predicate: Exposure trigger at the lower front area of the main body or remote switch.

(Difference: Location and external exposure switch. This does not affect the safety and effectiveness of the medical device.)

<Electrical/Performance Characteristics>
Exposure time
Subject Device: 0.04~2.0 seconds in .01-.40s increments (20 steps)
Predicate: 0.02~2.0 seconds in .01-.40s increments (20 steps)
(The difference does not affect the safety and effectiveness of the medical device)

Time accuracy
Subject Device: ±5% or ±20ms, whichever is greater
Predicate: ±5% or ±20ms, whichever is greater (Same)

mA
Subject Device: 2.5mA
Predicate: 2.5mA (Same)

kVp
Subject Device: 65kVp
Predicate: 65kVp (Same)

Waveform
Subject Device: Constant Potential (DC)
Predicate: Constant Potential (DC) (Same)

Total Filtration
Subject Device: 1.75mmA1 Predicate:
1.8mmA1
(The distance difference has no impact on safety and performance. Both devices conform to the same safety and performance standards.)

VII. 807.92(b): PERFORMANCE DATA

Electrical safety and electromagnetic compatibility (EMC) and EMT

The subject device conforms to the following Standards:

The Portable Dental X-ray Device is subject to the EPRC performance standards for diagnostic X-ray systems and their major components (21 CFR1020.30 and 1020.31) and complies with those standards.
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safetyand 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

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 protectionin diagnostic X-ray equipment

IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

IEC 60601-2-65 Edition 1.2 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 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes

IEC 62366 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices

ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices

The predicate device conforms to the following Standards (Standard versions not publicly available):

IEC 60601-1

IEC 60601-1-2

IEC 60601-1-3

IEC 60601-1-6

IEC 60601-2-65

IEC 62304

IEC 62366

ISO 14971

IEC 61223-3-4

Software Verification and Validation Testing

Software V&V was concluded in accordance with FDA's Guidance on "Content of Premarket Submissions for Device Software Functions," June 2023.

Animal Testing

Not applicable to demonstrate substantial equivalence.

Clinical Testing

A clinical image comparison study was conducted to qualitatively compare the image quality of the subject device, Portable Dental X-ray Device (model: GT-1) with the predicate device HyperLight Portable X-ray Unit. Six patients underwent standard intraoral radiographic examinations at multiple tooth positions. A licensed dental professional qualitatively evaluated paired images acquired from both devices. Under identical test conditions, the images obtained with GT-1 were judged to meet dental diagnostic standards, with image clarity and detail recognition

comparable to those of the predicate device. Therefore, the clinical data supports substantial equivalence in clinical image quality.

Bench Testing

Bench testing was performed to objectively characterize the imaging performance of the Portable Dental X-ray Device (Model: GT-1) when used with a compatible intraoral sensor. Portable Dental X-ray Device was evaluated with the PlutoX Digital Intraoral X-Ray Imaging System (model Pluto0001X; CMOS, 20 μm pixel pitch, specified limiting resolution 25 lp/mm, typical >14.5 lp/mm). Measurements followed IEC 62220-1-1 geometry with a source-to-image distance ≥1.5 m and an interpolated RQA4.5 radiation quality at 65 kVp with 6.1 mm Al HVL and 18.5 mm additional aluminum filtration derived from IEC 61267 RQA4 and RQA5. Slanted-edge images were used to calculate modulation transfer function (MTF), and flat-field images at the same exposure level were used to derive normalized noise power spectrum (NNPS) and detective quantum efficiency (DQE). The resulting objective image-quality metrics and key test conditions are summarized in the table below.

Item	Description / Condition	Measured / specified value
Beam quality	Interpolated RQA4.5 (IEC 61267)	65 kVp; HVL 6.1 mm Al; additional filtration 18.5 mm Al
Geometry	Source-to-image distance / positioning	SID ≥1.5 m; test object immediately in front of detector
Horizontal MTF	Slanted-edge method, RQA4.5	>70% at 8.5 lp/mm; >50% at 11.7 lp/mm; >30% at 15.2 lp/mm
Vertical MTF	Slanted-edge method, RQA4.5	>70% at 7.0 lp/mm; >50% at 10.12 lp/mm; >30% at 12.74 lp/mm
Practical spatial resolution	From MTF curves	≈15 lp/mm at 10% MTF; MTF falls toward 0 by ~20–25 lp/mm
NNPS	From flat-field images at same exposure level	High peak >1×10^{-4} at low spatial frequencies; decreases to ≈5×10^{-5} or less at high spatial frequencies
DQE	Calculated from MTF, NNPS and SNR^2_in (RQA4.5)	≈0.25 at low spatial frequency; decreases toward 0 by ~15 lp/mm

VIII. CONCLUSIONS

The overall comparison of intended use, technological characteristics and performance specifications demonstrate that subject device Portable Dental X-ray Device (Model: GT-1) is safe, effective and performs as well as the predicate device. Guilin Refine Medical Instrument Co., Ltd is of the opinion that Portable Dental X-ray Device (Model: GT-1) does not introduce any new significant potential safety risks and is substantially equivalent to the predicate device.