

K254018 Portable Dental X-ray Device (GT-1)Feb 19, 2026
66 days to decisionK254018 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k254018/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Dec 15, 2025
Decision date	Feb 19, 2026
Days to decision	66 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guilin Refine Medical Instrument Co., Ltd.
Location	Guangxi, CN
Contact	Su Qin
510(k) history	3 submissions · 3 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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