

K251438 Dental X-Ray Device (Ai Ray Lite, Ai Ray Pro, Master Ray)Sep 4, 2025
118 days to decisionK251438 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k251438/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	May 9, 2025
Decision date	Sep 4, 2025
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guilin Woodpecker Medical Instrument Co., Ltd.
Location	Flintville, TN, US
Contact	Yiwei Wang
510(k) history	14 submissions · 14 cleared · 2006-2025

REGULATORY CONSULTANT

Consulting firm	Irc
Contact	Charles Mack

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251438/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026