FDA 510(k) Premarket Notification

K251438 Dental X-Ray Device (Ai Ray Lite, Ai Ray Pro, Master Ray)

CLEARED

Sep 4, 2025
118 days to decision

K251438 · 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