

**K222569 Ai Ray Dental X-Ray Device**Nov 23, 2022  
91 days to decisionK222569 · Product code: **EHD** · Radiology  
Source: <https://www.510kdatabase.net/k222569/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Aug 24, 2022
Decision date	Nov 23, 2022
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guilin Woodpecker Medical Instrument Co., Ltd.</b>
Location	Flintville, TN, US
Contact	Xunxian Wu
510(k) history	14 submissions · 14 cleared · 2006-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Irc</b>
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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222569/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026