

K252110 Dental X-RAY Unit (AJX200)Mar 12, 2026
248 days to decisionK252110 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k252110/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Jul 7, 2025
Decision date	Mar 12, 2026
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Ajax Medical Equipment Co., Ltd.
Location	Guangzhou, CN
Contact	Sophia Xu
510(k) history	3 submissions · 3 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	Sgs-Cstc Standards Technical Services Co., Ltd.
Contact	Jett Lee

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/k252110/> 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