

**K250164 Cassette Autoclave (ACA5)**Aug 14, 2025  
205 days to decisionK250164 · Product code: **FLE** · General HospitalSource: <https://www.510kdatabase.net/k250164/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Jan 21, 2025
Decision date	Aug 14, 2025
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guangzhou Ajax Medical Equipment Co., Ltd.</b>
Location	Guangzhou, CN
Contact	Dien Wang
510(k) history	3 submissions · 3 cleared · 2021-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Sgs-Cstc Standards Technical Services Co., Ltd.</b>
Contact	Iris Fung

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/k250164/> 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 14, 2026