FDA 510(k) Premarket Notification

K250164 Cassette Autoclave (ACA5)

CLEARED

Aug 14, 2025
205 days to decision

K250164 · Product code: **FLE** · General Hospital
Source: https://www.510kdatabase.net/k250164/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Sgs-Cstc Standards Technical Services Co., Ltd.**
Contact	Iris Fung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov