

K243994 Steam Sterilizer (2545D)Jun 6, 2025
162 days to decisionK243994 · Product code: **FLE** · General Hospital
Source: <https://www.510kdatabase.net/k243994/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Dec 26, 2024
Decision date	Jun 6, 2025
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ningbo Ican Machines Co., Ltd.
Location	Ningbo, CN
Contact	Hui Lin
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Orscene (Shanghai) Medical Technology Co., Ltd.
Contact	Lord Guo

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

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