

K252843 STERRAD 100NX Sterilization System with ALLClear Technology (10104)

Apr 15, 2026
219 days to decision

K252843 · Product code: MLR · General Hospital
Source: <https://www.510kdatabase.net/k252843/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Chemical (MLR)
Date received	Sep 8, 2025
Decision date	Apr 15, 2026
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Advanced Sterilization Products, Inc.
Location	Irvin, CA, US
Contact	Brandon Roberts
510(k) history	5 submissions · 5 cleared · 2021-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k252843/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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