

K212174 STERRAD 100NX Sterilizer with ALLClear TechnologyOct 9, 2021
89 days to decisionK212174 · Product code: **MLR** · General Hospital
Source: <https://www.510kdatabase.net/k212174/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Chemical (MLR)
Date received	Jul 12, 2021
Decision date	Oct 9, 2021
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Advanced Sterilization Products, Inc.
Location	Irvin, CA, US
Contact	Summer Bowman
Website	https://www.asp.com/en-us
510(k) history	5 submissions · 5 cleared · 2021-2026

Advanced Sterilization Products, Inc. is a leader in sterilization and high-level disinfection solutions for healthcare facilities. The company develops sterilization systems, monitoring devices, and endoscope reprocessing equipment, with a manufacturing facility in Irvine, US. The company holds FDA 510(k) clearances from total submissions, with all cleared devices classified as General Hospital devices. The regulatory record spans from 2021 to 2026, with the most recent clearance in 2026 demonstrating continued product innovation and market activity. ASP's cleared portfo...
