

**K212200 STERLINK™ FPS-15s Plus Sterilizer with
STERLOAD™ Cassette**Oct 22, 2021
100 days to decisionK212200 · Product code: MLR · General Hospital
Source: <https://www.510kdatabase.net/k212200/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Chemical (MLR)
Date received	Jul 14, 2021
Decision date	Oct 22, 2021
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Plasmapp Co.,, Ltd.
Location	Daejeon, KR
Contact	LEE Seung Hun
510(k) history	8 submissions · 8 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	CardioMed Device Consultants, LLC
Contact	Candace Cederman

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.netDevice record: <https://www.510kdatabase.net/k212200/>; Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026