

K211748 Selux AST SystemApr 19, 2023
681 days to decisionK211748 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k211748/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Jun 7, 2021
Decision date	Apr 19, 2023
Days to decision	681 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Model AST Gen 1.0

APPLICANT

Company	Selux Diagnostics, Inc.
Location	Charlestown, MA, US
Contact	Eric Stern
510(k) history	4 submissions · 4 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Pbo Consulting
Contact	Patricia Shrader

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/k211748/> 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 27, 2026