FDA 510(k) Premarket Notification

K211759 Selux AST System

CLEARED

Jan 18, 2023
590 days to decision

K211759 · Product code: **LON** · Microbiology
Source: https://www.510kdatabase.net/k211759/

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	Jan 18, 2023
Days to decision	590 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