FDA 510(k) Premarket Notification

K223493 PBC Separator with Selux AST System

CLEARED

Feb 15, 2024
451 days to decision

K223493 · Product code: **QZX** · Microbiology
Source: https://www.510kdatabase.net/k223493/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Positive Blood Culture Processor For Inoculum Preparation Used For Antimicrobial Susceptibility Testing (QZX)
Date received	Nov 21, 2022
Decision date	Feb 15, 2024
Days to decision	451 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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	Carrene Plummer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov