

K244044 PBC Separator with Selux AST SystemMar 28, 2025
88 days to decisionK244044 · Product code: **QZX** · Microbiology
Source: <https://www.510kdatabase.net/k244044/>**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 | Dec 30, 2024 |
| Decision date | Mar 28, 2025 |
| Days to decision | 88 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k244044/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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