

K250513 IntelliSep Test (CV-ICG-048)Mar 21, 2025
28 days to decisionK250513 · Product code: **QUT** · Microbiology
Source: <https://www.510kdatabase.net/k250513/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Deformability Cytometry For Sepsis Risk Assessment (QUT)
Date received	Feb 21, 2025
Decision date	Mar 21, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cytovale, Inc.
Location	San Francisco, CA, US
Contact	Sarah Esterquest
510(k) history	3 submissions · 3 cleared · 2022-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250513/> 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 14, 2026