FDA 510(k) Premarket Notification

K250912 IntelliSep Test

CLEARED

Nov 19, 2025
237 days to decision

K250912 · Product code: **QUT** · Microbiology
Source: https://www.510kdatabase.net/k250912/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Deformability Cytometry For Sepsis Risk Assessment (QUT)
Date received	Mar 27, 2025
Decision date	Nov 19, 2025
Days to decision	237 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