FDA 510(k) Premarket Notification

K220991 IntelliSep test

CLEARED

Dec 20, 2022
260 days to decision

K220991 · Product code: **QUT** · Microbiology
Source: https://www.510kdatabase.net/k220991/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Deformability Cytometry For Sepsis Risk Assessment (QUT)
Date received	Apr 4, 2022
Decision date	Dec 20, 2022
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

CLINICAL EVIDENCE - NCT04933760

CV-SQuISH-ED: Clinical Validation Study

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	599 patients (actual)
Study sites	4 sites
Condition studied	Sepsis; Infection
Study type	Observational
Completion date	May 1, 2022
Sponsor	Cytovale, Inc. (Industry)

Primary outcome

IntelliSep Index versus Retrospective Physician Diagnosis (RPD) per the sepsis 3 definition

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04933760