FDA 510(k) Premarket Notification

CLEARED

K232095 SeptiCyte RAPID

Dec 15, 2023
155 days to decision

K232095 · Product code: **PRE** · Microbiology
Source: https://www.510kdatabase.net/k232095/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rt-qpcr Assay For Mrna Transcript Immune Biomarkers (PRE)
Date received	Jul 13, 2023
Decision date	Dec 15, 2023
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Immunexpress, Inc.**
Location	Seattle, WA, US
Contact	LaKesha Hunt-Dickens
510(k) history	3 submissions · 3 cleared · 2017-2023

CLINICAL EVIDENCE - NCT01905033

Molecular Diagnosis and Risk Stratification of Sepsis

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	7500 patients (estimated)
Study sites	2 sites
Condition studied	Sepsis
Study type	Observational
Completion date	Jun 1, 2018
Sponsor	Academisch Medisch Centrum - Universiteit van Amsterdam (AMC-UvA) (Other)

Primary outcome

Molecular information about causative pathogens and the host response in patients with sepsis

Secondary outcome

Stratification of septic patients by severity and type of immune response to infection

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT01905033