

K163260 SeptiCyte LABFeb 17, 2017
88 days to decisionK163260 · Product code: **PRE** · Microbiology
Source: <https://www.510kdatabase.net/k163260/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rt-qpcr Assay For Mrna Transcript Immune Biomarkers (PRE)
Date received	Nov 21, 2016
Decision date	Feb 17, 2017
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Immunexpress, Inc.
Location	Seattle, WA, US
Contact	VICTORIA ROTHWELL
510(k) history	3 submissions · 3 cleared · 2017-2023

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