

K181663 ePlex Blood Culture Identification Panel - Gram Positive (BCID-GP) PanelDec 20, 2018
178 days to decisionK181663 · Product code: **PAM** · Microbiology
Source: <https://www.510kdatabase.net/k181663/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gram-positive Bacteria And Their Resistance Markers (PAM)
Date received	Jun 25, 2018
Decision date	Dec 20, 2018
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genmark Diagnostics, Incorporated
Location	Carlsbad, CA, US
Contact	Alan Maderazo
510(k) history	7 submissions · 7 cleared · 2016-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181663/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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