

K182619 ePlex Blood Culture Identification Gram Negative (BCID-GN) PanelApr 12, 2019
200 days to decisionK182619 · Product code: **PEN** · Microbiology
Source: <https://www.510kdatabase.net/k182619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gram-negative Bacteria And Associated Resistance Markers (PEN)
Date received	Sep 24, 2018
Decision date	Apr 12, 2019
Days to decision	200 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/k182619/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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