

**K213236 ePlex Blood Culture Identification Gram Negative (BCID-GN) Panel**Apr 27, 2022  
209 days to decisionK213236 · Product code: **PEN** · Microbiology  
Source: <https://www.510kdatabase.net/k213236/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gram-negative Bacteria And Associated Resistance Markers (PEN)
Date received	Sep 30, 2021
Decision date	Apr 27, 2022
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213236/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026