

K182690 ePlex Blood Culture Identification Panel Fungal Pathogen (BCID-FP) PanelDec 21, 2018
85 days to decisionK182690 · Product code: **PEO** · Microbiology
Source: <https://www.510kdatabase.net/k182690/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fungal Organisms, Nucleic Acid-based Assay (PEO)
Date received	Sep 27, 2018
Decision date	Dec 21, 2018
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182690/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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