

K162950 VITEK MSJul 22, 2017
271 days to decisionK162950 · Product code: **PEX** · Microbiology
Source: <https://www.510kdatabase.net/k162950/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Mass Spectrometry, Maldi Tof, Microorganism Identification, Cultured Isolates (PEX)
Date received	Oct 24, 2016
Decision date	Jul 22, 2017
Days to decision	271 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	bioMerieux, Inc.
Location	Mchenry, IL, US
Contact	Nathan Hardesty
510(k) history	251 submissions · 250 cleared · 1983-2026

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