

K181412 VITEK MSDec 21, 2018
205 days to decisionK181412 · Product code: **QBN** · Microbiology
Source: <https://www.510kdatabase.net/k181412/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mass Spectrometry, Maldi Tof, Microorganism Identification, Cultured Isolates (QBN)
Date received	May 30, 2018
Decision date	Dec 21, 2018
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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