

K163563 VITEK 2 AST-GN Gentamicin (<=1 – >=16 µg/mL)

Mar 13, 2017
84 days to decision

K163563 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k163563/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Dec 19, 2016
Decision date	Mar 13, 2017
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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