FDA 510(k) Premarket Notification

K192110 Vitek Densichek

CLEARED

Oct 31, 2019
87 days to decision

K192110 · Product code: **LON** · Microbiology
Source: https://www.510kdatabase.net/k192110/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Aug 5, 2019
Decision date	Oct 31, 2019
Days to decision	87 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