

K162385 RAPIDEC CARBA NPApr 27, 2017
245 days to decisionK162385 · Product code: **PTJ** · Microbiology
Source: <https://www.510kdatabase.net/k162385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Phenotypic Test Kit, Non-susceptible/elevated Mic Organisms, Cultured Isolates (PTJ)
Date received	Aug 25, 2016
Decision date	Apr 27, 2017
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomerieux S.A.
Location	Craponne, FR
Contact	ASA KARLSSON
510(k) history	16 submissions · 16 cleared · 2011-2025

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