

K162827 VIDAS B.R.A.H.M.S. PCT (PCT)Feb 23, 2017
139 days to decisionK162827 · Product code: **PRI** · Microbiology
Source: <https://www.510kdatabase.net/k162827/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Procalcitonin Assay (PRI)
Date received	Oct 7, 2016
Decision date	Feb 23, 2017
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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