

K160911 VIDAS B.R.A.H.M.S. PCT (PCT)

Jun 28, 2016
88 days to decision

K160911 · Product code: **PMT** · Microbiology
Source: <https://www.510kdatabase.net/k160911/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device To Detect And Measure Procalcitonin (pct) In Human Clinical Specimens (PMT)
Date received	Apr 1, 2016
Decision date	Jun 28, 2016
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	bioMerieux, Inc.
Location	Mchenry, IL, US
Contact	Thi My Lan Dang
510(k) history	251 submissions · 250 cleared · 1983-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k160911/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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