

K080017 VIDAS AFP ASSAYSep 26, 2008
267 days to decisionK080017 · Product code: **LOJ** · Immunology
Source: <https://www.510kdatabase.net/k080017/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test,alpha-fetoprotein For Testicular Cancer (LOJ)
Date received	Jan 3, 2008
Decision date	Sep 26, 2008
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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