

K080469 VIDAS CA 15-3 ASSAYJun 22, 2009
487 days to decisionK080469 · Product code: **LTK** · Immunology
Source: <https://www.510kdatabase.net/k080469/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Feb 21, 2008
Decision date	Jun 22, 2009
Days to decision	487 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080469/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 22, 2026