

K080561 VIDAS CA 125 II ASSAYApr 10, 2009
407 days to decisionK080561 · Product code: **LTK** · Immunology
Source: <https://www.510kdatabase.net/k080561/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Feb 28, 2008
Decision date	Apr 10, 2009
Days to decision	407 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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