

K965092 VIDAS ROTAVIRUS ASSAYMay 5, 1997
137 days to decisionK965092 · Product code: **LIQ** · Microbiology
Source: <https://www.510kdatabase.net/k965092/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rotavirus (LIQ)
Date received	Dec 19, 1996
Decision date	May 5, 1997
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomerieux Vitek, Inc.
Location	Hazelwood, MO, US
Contact	TERRY MCGOVERN
510(k) history	49 submissions · 49 cleared · 1992-1998

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