

K964424 ROTAVIRUS EIAAug 8, 1997
276 days to decisionK964424 · Product code: **LIQ** · Microbiology
Source: <https://www.510kdatabase.net/k964424/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rotavirus (LIQ)
Date received	Nov 5, 1996
Decision date	Aug 8, 1997
Days to decision	276 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Trinity Biotech, Inc.
Location	Jamestown, NY, US
Contact	GRACE HOLLAND
510(k) history	2 submissions · 2 cleared · 1997-2003

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