

K854129 ROTALEX 2 LATEX AGGLUTINATION TEST FOR ROTAVIRUSJan 21, 1986
104 days to decisionK854129 · Product code: **LIQ** · Microbiology
Source: <https://www.510kdatabase.net/k854129/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rotavirus (LIQ)
Date received	Oct 9, 1985
Decision date	Jan 21, 1986
Days to decision	104 days
Third-party review	No

APPLICANT

Company	Orion Diagnostica, Inc.
Location	Mchenry, IL, US
Contact	DE MARCO
510(k) history	28 submissions · 28 cleared · 1980-1994

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