

K883935 ORTHO* ROTAVIRUS ANTIGEN ELISA TESTJan 4, 1989
107 days to decisionK883935 · Product code: **LIQ** · Microbiology
Source: <https://www.510kdatabase.net/k883935/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rotavirus (LIQ)
Date received	Sep 19, 1988
Decision date	Jan 4, 1989
Days to decision	107 days
Third-party review	No

APPLICANT

Company	Ortho Diagnostic Systems, Inc.
Location	Carpinteria, CA, US
Contact	MCCLAIN, PHD
510(k) history	126 submissions · 126 cleared · 1981-1997

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