FDA 510(k) Premarket Notification

K841319 ROTALEX LATEX AGGLUTINATION TEST

CLEARED

Sep 14, 1984
165 days to decision

K841319 · Product code: **LIQ** · Microbiology
Source: https://www.510kdatabase.net/k841319/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rotavirus (LIQ)
Date received	Apr 2, 1984
Decision date	Sep 14, 1984
Days to decision	165 days
Third-party review	No

APPLICANT

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