

**K942286 DIARLEX ROTA-ADENO**Dec 14, 1994  
236 days to decisionK942286 · Product code: **LIQ** · Microbiology  
Source: <https://www.510kdatabase.net/k942286/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rotavirus (LIQ)
Date received	Apr 22, 1994
Decision date	Dec 14, 1994
Days to decision	236 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Orion Diagnostica, Inc.</b>
Location	Mchenry, IL, US
Contact	TIMO RAINES
510(k) history	28 submissions · 28 cleared · 1980-1994

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k942286/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026