

**K853554 PATHFINDER DIRECT ANTIGEN DETECTION SYS
ROTAVIRUS**Nov 26, 1985
92 days to decisionK853554 · Product code: **LIQ** · Microbiology
Source: <https://www.510kdatabase.net/k853554/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Linked Immunoabsorbent Assay, Rotavirus (LIQ) |
| Date received | Aug 26, 1985 |
| Decision date | Nov 26, 1985 |
| Days to decision | 92 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Kallestad Laboratories, Inc. |
| Location | Mchenry, IL, US |
| Contact | KATIA BRESLAWEC |
| 510(k) history | 92 submissions · 92 cleared · 1976-1986 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k853554/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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