

K864645 ADENOLEX (R) LATEX AGGLUTINATION TESTJun 4, 1987
191 days to decisionK864645 · Product code: **GOD** · Microbiology
Source: <https://www.510kdatabase.net/k864645/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antigens, Cf (including Cf Control), Adenovirus 1-33 (GOD) |
| Date received | Nov 25, 1986 |
| Decision date | Jun 4, 1987 |
| Days to decision | 191 days |
| Third-party review | No |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k864645/>; Data sourced from FDA 510(k) public records (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. - Generated June 30, 2026