

K905612 VENTREX COATED TUBE IGE RADIOIMMUNOASSAYFeb 21, 1991
69 days to decisionK905612 · Product code: **DGC** · Immunology
Source: <https://www.510kdatabase.net/k905612/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ige, Antigen, Antiserum, Control (DGC) |
| Date received | Dec 14, 1990 |
| Decision date | Feb 21, 1991 |
| Days to decision | 69 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Ventrex Laboratories, Inc. |
| Location | Mchenry, IL, US |
| Contact | JAMES W CHAMPLIN |
| 510(k) history | 82 submissions · 82 cleared · 1979-1992 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k905612/>; 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 29, 2026