

K864696 ALLERG*ENS ENZYME IMMUNOASSAY KITMar 17, 1987
106 days to decisionK864696 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k864696/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Radioallergosorbent (rast) Immunological (DHB) |
| Date received | Dec 1, 1986 |
| Decision date | Mar 17, 1987 |
| Days to decision | 106 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Dexall Biomedical Labs, Inc. |
| Location | Gaithersburg, MD, US |
| Contact | HUBSCHER, PHD |
| 510(k) history | 4 submissions · 4 cleared · 1985-1989 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k864696/>; 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