

**K901859 COAT-A-COUNT TOTAL IGE IRMA, CATALOG #IKIE1,
IKIE2**May 3, 1990
9 days to decisionK901859 · Product code: JHR · Immunology
Source: <https://www.510kdatabase.net/k901859/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Immunoglobulins (d, E) (JHR) |
| Date received | Apr 24, 1990 |
| Decision date | May 3, 1990 |
| Days to decision | 9 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |

APPLICANT

| | |
|----------------|---|
| Company | Diagnostic Products Corp. |
| Location | Mchenry, IL, US |
| Contact | B ASARCH,PHD |
| 510(k) history | 321 submissions · 321 cleared · 1976-2006 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k901859/> 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 21, 2026