

**K850574 DADE IMMU-TRACE TRI-RAC R TRI-LEVEL
IMMUNOASSAY CO**Apr 12, 1985
58 days to decisionK850574 · Product code: JJY · Immunology
Source: <https://www.510kdatabase.net/k850574/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Feb 13, 1985
Decision date	Apr 12, 1985
Days to decision	58 days
Third-party review	No

APPLICANT

Company	American Dade
Location	Mchenry, IL, US
Contact	JAMES E KELLER
510(k) history	149 submissions · 149 cleared · 1980-1987

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k850574/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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