

K853943 CRITIC C LEVEL I & IIDec 23, 1985
90 days to decisionK853943 · Product code: **JJY** · Immunology
Source: <https://www.510kdatabase.net/k853943/>**SUBMISSION DETAILS**

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|-----------------------|---------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Multi-analyte Controls, All Kinds (assayed) (JJY) |
| Date received | Sep 24, 1985 |
| Decision date | Dec 23, 1985 |
| Days to decision | 90 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Dimension Diagnostics |
| Location | St. Charles, MO, US |
| Contact | CLYDE E HAM |
| 510(k) history | 8 submissions · 8 cleared · 1985-1987 |

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