

**K950802 LINICAL PROTEIN I CALIBRATION VERIFIERS
LEVELS A - FOR BECKMAN ARRAY 360 SYSTEM**Jun 1, 1995
100 days to decisionK950802 · Product code: JJY · Immunology
Source: <https://www.510kdatabase.net/k950802/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Multi-analyte Controls, All Kinds (assayed) (JJY) |
| Date received | Feb 21, 1995 |
| Decision date | Jun 1, 1995 |
| Days to decision | 100 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | International Enzymes, Inc. |
| Location | Fallbrook, CA, US |
| Contact | TEVA C ROTHWELL |
| 510(k) history | 7 submissions · 7 cleared · 1994-2001 |

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