

K863053 ALT S.C.E. (GPT)Dec 10, 1986
120 days to decisionK863053 · Product code: **CKA** · Chemistry
Source: <https://www.510kdatabase.net/k863053/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Nadh Oxidation/nad Reduction, Alt/sgpt (CKA) |
| Date received | Aug 12, 1986 |
| Decision date | Dec 10, 1986 |
| Days to decision | 120 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | J. D. Assoc. |
| Location | Montclair, NJ, US |
| Contact | DI PIETRO |
| 510(k) history | 34 submissions · 34 cleared · 1986-1987 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k863053/>; 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 29, 2026