

K823213 DIAGNOSTICS ALKALINE PHOSPHATASE OPTIMINov 22, 1982
25 days to decisionK823213 · Product code: **CJE** · Chemistry
Source: <https://www.510kdatabase.net/k823213/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (CJE) |
| Date received | Oct 28, 1982 |
| Decision date | Nov 22, 1982 |
| Days to decision | 25 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Boehringer Mannheim Corp. |
| Location | Mchenry, IL, US |
| 510(k) history | 340 submissions · 340 cleared · 1976-1999 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k823213/> 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 May 22, 2026