

**K821870 ULTRAZYME PLUS ALP**Jul 13, 1982  
18 days to decisionK821870 · Product code: **CJE** · Chemistry  
Source: <https://www.510kdatabase.net/k821870/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (CJE)
Date received	Jun 25, 1982
Decision date	Jul 13, 1982
Days to decision	18 days
Third-party review	No

**APPLICANT**

---

Company	<b>Harleco Diagnostics</b>
Location	Mchenry, IL, US
510(k) history	23 submissions · 23 cleared · 1976-1982

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k821870/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026