

K780095 ULTRAZYME PLUS ALPFeb 13, 1978
26 days to decisionK780095 · Product code: **CJE** · Chemistry
Source: <https://www.510kdatabase.net/k780095/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (CJE)
Date received	Jan 18, 1978
Decision date	Feb 13, 1978
Days to decision	26 days
Third-party review	No

APPLICANT

Company	Harleco
Location	Mchenry, IL, US
510(k) history	116 submissions · 116 cleared · 1976-1982

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Device record: <https://www.510kdatabase.net/k780095/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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