

**K821883 ULTRAZYME PLUS CK-I**Jul 14, 1982  
19 days to decisionK821883 · Product code: **CGS** · Chemistry  
Source: <https://www.510kdatabase.net/k821883/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Jun 25, 1982
Decision date	Jul 14, 1982
Days to decision	19 days
Third-party review	No

**APPLICANT**

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

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Device record: <https://www.510kdatabase.net/k821883/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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