

K780100 ULTRAZYME PLUS CK-1Mar 9, 1978
48 days to decisionK780100 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k780100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Jan 20, 1978
Decision date	Mar 9, 1978
Days to decision	48 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/k780100/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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