

K771389 CK-1 ULTRAZYME PLUSSep 2, 1977
37 days to decisionK771389 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k771389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Jul 27, 1977
Decision date	Sep 2, 1977
Days to decision	37 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k771389/> 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 14, 2026