

K821876 ULTRAZYME PLUS GOTJul 13, 1982
18 days to decisionK821876 · Product code: **CIT** · Chemistry
Source: <https://www.510kdatabase.net/k821876/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nadh Oxidation/nad Reduction, Ast/sgot (CIT)
Date received	Jun 25, 1982
Decision date	Jul 13, 1982
Days to decision	18 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k821876/> 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