

K772028 GEMSAEC APPLI. FOR ULTRAZYME PLUS LDHNov 15, 1977
19 days to decisionK772028 · Product code: **CFJ** · Chemistry
Source: <https://www.510kdatabase.net/k772028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Lactate Dehydrogenase (CFJ)
Date received	Oct 27, 1977
Decision date	Nov 15, 1977
Days to decision	19 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.netDevice record: <https://www.510kdatabase.net/k772028/> 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