

K854585 ULTRAZYME PLUS & SYSTEMATE LDHDec 5, 1985
17 days to decisionK854585 · Product code: **CFJ** · Chemistry
Source: <https://www.510kdatabase.net/k854585/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Lactate Dehydrogenase (CFJ)
Date received	Nov 18, 1985
Decision date	Dec 5, 1985
Days to decision	17 days
Third-party review	No

APPLICANT

Company	Em Diagnostic Systems, Inc.
Location	Walker, MI, US
Contact	RAYMOND L MILLER
510(k) history	288 submissions · 288 cleared · 1984-1994

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