

K843269 SYSTEMATE LDH, 67210Sep 13, 1984
24 days to decisionK843269 · Product code: **CFJ** · Chemistry
Source: <https://www.510kdatabase.net/k843269/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Lactate Dehydrogenase (CFJ)
Date received	Aug 20, 1984
Decision date	Sep 13, 1984
Days to decision	24 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k843269/> 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