

K842669 TITAN GEL ISO DOT LDH KITNov 9, 1984
122 days to decisionK842669 · Product code: **CFE** · Chemistry
Source: <https://www.510kdatabase.net/k842669/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic, Lactate Dehydrogenase Isoenzymes (CFE)
Date received	Jul 10, 1984
Decision date	Nov 9, 1984
Days to decision	122 days
Third-party review	No

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
Contact	ERIC PETERSEN
510(k) history	280 submissions · 280 cleared · 1978-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k842669/>; 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