

**K852391 EDC/TITAN GELISO-DOT TOTAL LDH ISOENZYME
PROCEDURE**Oct 1, 1985
118 days to decisionK852391 · Product code: **CFH** · Chemistry
Source: <https://www.510kdatabase.net/k852391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tetrazolium Int Dye-diaphorase, Lactate Dehydrogenase (CFH)
Date received	Jun 5, 1985
Decision date	Oct 1, 1985
Days to decision	118 days
Third-party review	No

APPLICANT

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

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