

**K892818 REP(TM) LD-2 STAT KIT, CAT. NO. 3078**Jun 20, 1989  
64 days to decisionK892818 · Product code: **CFE** · Chemistry  
Source: <https://www.510kdatabase.net/k892818/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic, Lactate Dehydrogenase Isoenzymes (CFE)
Date received	Apr 17, 1989
Decision date	Jun 20, 1989
Days to decision	64 days
Third-party review	No

**APPLICANT**

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Company	<b>Helena Laboratories</b>
Location	Mchenry, IL, US
Contact	PAT FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

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