

**K020467 SPIFE LD VIS ISOENZYME KIT, MODELS 3450, 3451,
AND 3452**Mar 29, 2002
45 days to decisionK020467 · Product code: **CFE** · Chemistry
Source: <https://www.510kdatabase.net/k020467/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic, Lactate Dehydrogenase Isoenzymes (CFE)
Date received	Feb 12, 2002
Decision date	Mar 29, 2002
Days to decision	45 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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