

K022757 SPIFE CK KIT, MODEL 3332, 3333Oct 11, 2002
52 days to decisionK022757 · Product code: **JHY** · Chemistry
Source: <https://www.510kdatabase.net/k022757/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetric Method, Cpk Or Isoenzymes (JHY)
Date received	Aug 20, 2002
Decision date	Oct 11, 2002
Days to decision	52 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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