

K020625 SPIFE 2000/3000 ALP 40, 20May 6, 2002
69 days to decisionK020625 · Product code: **CIN** · Chemistry
Source: <https://www.510kdatabase.net/k020625/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic Separation, Alkaline Phosphatase Isoenzymes (CIN)
Date received	Feb 26, 2002
Decision date	May 6, 2002
Days to decision	69 days
Third-party review	No
Summary / Statement	Statement
Other names	MODELS 3345 AND 3346

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k020625/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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