

K964453 REP 3 FLUR SPE-60 KITDec 23, 1996
47 days to decisionK964453 · Product code: **CEF** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic, Protein Fractionation (CEF)
Date received	Nov 6, 1996
Decision date	Dec 23, 1996
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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