

**K913058 REP(TM) SPE TEMP-30-16-8 PROCEDURE,  
3170,3171,3172**Oct 30, 1991  
112 days to decisionK913058 · Product code: **CEF** · Chemistry  
Source: <https://www.510kdatabase.net/k913058/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic, Protein Fractionation (CEF)
Date received	Jul 10, 1991
Decision date	Oct 30, 1991
Days to decision	112 days
Third-party review	No
Summary / Statement	Statement

**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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913058/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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