

**K892424 REP SPE HI-RES SYSTEM NO. 3176, 3177, 3178**Jun 9, 1989  
60 days to decisionK892424 · Product code: **CFF** · Chemistry  
Source: <https://www.510kdatabase.net/k892424/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoelectrophoretic, Immunoglobulins, (g, A, M) (CFF)
Date received	Apr 10, 1989
Decision date	Jun 9, 1989
Days to decision	60 days
Third-party review	No

**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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