

K973040 SPIFE IFE-6Jan 2, 1998
141 days to decisionK973040 · Product code: **CFF** · Chemistry
Source: <https://www.510kdatabase.net/k973040/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immuno-electrophoretic, Immunoglobulins, (g, A, M) (CFF)
Date received	Aug 14, 1997
Decision date	Jan 2, 1998
Days to decision	141 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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