

**K111369 THE HELENA V8 IMMUNODISPLACEMENT KIT**Jun 26, 2012  
407 days to decisionK111369 · Product code: **CFF** · Immunology  
Source: <https://www.510kdatabase.net/k111369/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immuno-electrophoretic, Immunoglobulins, (g, A, M) (CFF)
Date received	May 16, 2011
Decision date	Jun 26, 2012
Days to decision	407 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Helena Laboratories Uk, Ltd.</b>
Location	Beaumont, TX, US
Contact	PATRICIA FRANKS
510(k) history	1 submissions · 1 cleared · 2012-2012

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