

**K132978 IMPACT DX FACTOR V LEIDEN AND FACTOR II  
GENOTYPING TEST**Jun 13, 2014  
263 days to decisionK132978 · Product code: **PHJ** · Pathology  
Source: <https://www.510kdatabase.net/k132978/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Mass Spectrometry, Multiplex Genotyping, Hereditary Thrombophilia Related Mutations (PHJ)
Date received	Sep 23, 2013
Decision date	Jun 13, 2014
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sequenom, Inc.</b>
Location	San Diego, CA, US
Contact	Robin Weiner
Website	<a href="http://www.sequenom.com/">http://www.sequenom.com/</a>
510(k) history	1 submissions · 1 cleared · 2014-2014

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