

K093974 ESENR FII-FV-MTHFR GENOTYPING TEST, ESENR FII-FV GENOTYPING TEST, ESENR FII GENOTYPINGApr 22, 2010
120 days to decisionK093974 · Product code: **NPQ** · Pathology
Source: <https://www.510kdatabase.net/k093974/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Factor V Leiden Mutations, Genomic Dna Pcr (NPQ)
Date received	Dec 23, 2009
Decision date	Apr 22, 2010
Days to decision	120 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Osmetech Molecular Diagnostics
Location	Pasadena, CA, US
Contact	ROBERT S DICHECK
510(k) history	3 submissions · 3 cleared · 2008-2010

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