

K060564 INFINITI SYSTEMFeb 7, 2007
341 days to decisionK060564 · Product code: **NPQ** · Pathology
Source: <https://www.510kdatabase.net/k060564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Factor V Leiden Mutations, Genomic Dna Pcr (NPQ)
Date received	Mar 3, 2006
Decision date	Feb 7, 2007
Days to decision	341 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	AutoGenomics, Inc.
Location	Carlsbad, CA, US
Contact	EVELYN LOPEZ
510(k) history	1 submissions · 1 cleared · 2007-2007

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