

**K124006 ILLUMINA MISEQDX CYSTIC FIBROSIS 139-VARIANT  
ASSAY**Nov 19, 2013  
328 days to decisionK124006 · Product code: **PFR** · Pathology  
Source: <https://www.510kdatabase.net/k124006/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Cystic Fibrosis Transmembrane Conductance Regulator Gene, Mutations & Variants Panel Sequencing Detection (PFR)
Date received	Dec 26, 2012
Decision date	Nov 19, 2013
Days to decision	328 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Illumina, Inc.</b>
Location	San Diego, CA, US
Contact	LEANNE M KIVIHARJU
Website	<a href="http://www.illumina.com/">http://www.illumina.com/</a>
510(k) history	6 submissions · 4 cleared · 2010-2013

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