

**K132750 ILLUMINA MISEQDX CYSTIC FIBROSIS CLINICAL SEQUENCING ASSAY**Nov 19, 2013  
77 days to decisionK132750 · Product code: **PFS** · Pathology  
Source: <https://www.510kdatabase.net/k132750/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Cystic Fibrosis Transmembrane Conductance Regulator Gene, Variant Gene Sequence Detection (PFS)
Date received	Sep 3, 2013
Decision date	Nov 19, 2013
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132750/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026