

**K062028 CYSTIC FIBROSIS GENOTYPING ASSAY, MODEL  
6L20-01**Sep 7, 2007  
416 days to decisionK062028 · Product code: **NUA** · Pathology  
Source: <https://www.510kdatabase.net/k062028/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Cystic Fibrosis Transmembrane Conductance Regulator, Gene Mutation Detection (NUA)
Date received	Jul 18, 2006
Decision date	Sep 7, 2007
Days to decision	416 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Celera Diagnostics</b>
Location	Alameda, CA, US
Contact	VICTORIA MACKINNON
510(k) history	1 submissions · 1 cleared · 2007-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062028/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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