

K063787 INPLEX CF MOLECULAR TESTMar 13, 2008
448 days to decisionK063787 · Product code: **NUA** · Pathology
Source: <https://www.510kdatabase.net/k063787/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Cystic Fibrosis Transmembrane Conductance Regulator, Gene Mutation Detection (NUA)
Date received	Dec 21, 2006
Decision date	Mar 13, 2008
Days to decision	448 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Third Wave Technologies, Inc.
Location	Madison, WI, US
Contact	ANDREW A LUKOWIAK
510(k) history	2 submissions · 2 cleared · 2005-2008

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