

**K083294 VERIGENE CFTR NUCLEIC ACID TEST AND
VERIGENE CFTR POLYT NUCLEIC ACID TEST**Jul 24, 2009
256 days to decisionK083294 · Product code: **NUA** · Pathology
Source: <https://www.510kdatabase.net/k083294/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Cystic Fibrosis Transmembrane Conductance Regulator, Gene Mutation Detection (NUA)
Date received	Nov 10, 2008
Decision date	Jul 24, 2009
Days to decision	256 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Nanosphere, Inc.
Location	Northbrook, IL, US
Contact	GREGORT W SHIPP
510(k) history	16 submissions · 15 cleared · 2007-2015

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