

K090901 ESENSOR CF GENOTYPING TESTM ESENSOR SYSTEM, ESENSOR CYSTIC FIBROSIS GENOTYPING TEST, ESENSOR INSTRUMENT, MODELS XT-8Jul 6, 2009
96 days to decisionK090901 · Product code: **NUA** · Pathology
Source: <https://www.510kdatabase.net/k090901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Cystic Fibrosis Transmembrane Conductance Regulator, Gene Mutation Detection (NUA)
Date received	Apr 1, 2009
Decision date	Jul 6, 2009
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osmetech Molecular Diagnostics
Location	Pasadena, CA, US
Contact	ROBERT S DICHECK
510(k) history	3 submissions · 3 cleared · 2008-2010

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