

K051435 ESENSOR CYSTIC FIBROSIS CARRIER DETECTION TEST , ESENSOR 4800 DNA DETECTION SYSTEM, MODEL 4800Jan 19, 2006
232 days to decisionK051435 · Product code: **NUA** · Pathology
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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	Jun 1, 2005
Decision date	Jan 19, 2006
Days to decision	232 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Clinical Micro Sensors
Location	Pasadena, CA, US
Contact	WILLIAM A COTY
510(k) history	1 submissions · 1 cleared · 2006-2006

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