

K121942 ADENOVIRUS R-GENE USFeb 8, 2013
221 days to decisionK121942 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k121942/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Jul 2, 2012
Decision date	Feb 8, 2013
Days to decision	221 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Argene SA
Location	Varilhes, FR
Contact	ERIC BRISSON
510(k) history	1 submissions · 1 cleared · 2013-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121942/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026