

K151690 Alere i Instrument, Alere i Influenza A & B, Alere i Strep A

Jul 16, 2015
23 days to decision

K151690 · Product code: **OOI** · Microbiology
Source: <https://www.510kdatabase.net/k151690/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Real Time Nucleic Acid Amplification System (OOI)
Date received	Jun 23, 2015
Decision date	Jul 16, 2015
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alere Scarborough, Inc.
Location	Scarborough, ME, US
Contact	Angela Drysdale
510(k) history	17 submissions · 16 cleared · 2012-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k151690/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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