

**K141757 ALERE I STREP A**Mar 31, 2015  
274 days to decisionK141757 · Product code: **PGX** · Microbiology  
Source: <https://www.510kdatabase.net/k141757/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Groups A, C And G Beta-hemolytic Streptococcus Nucleic Acid Amplification System (PGX)
Date received	Jun 30, 2014
Decision date	Mar 31, 2015
Days to decision	274 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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