

**K173653 Alere i Strep A 2, Alere i instrument, Alere i Strep A 2 Control Swab Kit**

May 2, 2018  
155 days to decision

K173653 · Product code: **PGX** · Microbiology  
Source: <https://www.510kdatabase.net/k173653/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Groups A, C And G Beta-hemolytic Streptococcus Nucleic Acid Amplification System (PGX)
Date received	Nov 28, 2017
Decision date	May 2, 2018
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k173653/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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