

**K143651 Simplexa Group A Strep Direct, Simplexa Group A Strep Positive Control Pack**Mar 18, 2015  
85 days to decisionK143651 · Product code: **PGX** · Microbiology  
Source: <https://www.510kdatabase.net/k143651/>**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	Dec 23, 2014
Decision date	Mar 18, 2015
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Focus Diagnostics, Inc.</b>
Location	Cypress, CA, US
Contact	Sharon Young
510(k) history	14 submissions · 13 cleared · 2007-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143651/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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