

K141338 LIAT STREP A ASSAYNov 4, 2014
167 days to decisionK141338 · Product code: **PGX** · Microbiology
Source: <https://www.510kdatabase.net/k141338/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Groups A, C And G Beta-hemolytic Streptococcus Nucleic Acid Amplification System (PGX)
Date received	May 21, 2014
Decision date	Nov 4, 2014
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Iquum, Inc.
Location	Marlborough, MA, US
Contact	Lingjun Chen
510(k) history	3 submissions · 3 cleared · 2011-2016

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