

K183366 GenePOC Strep AMar 6, 2019
92 days to decisionK183366 · Product code: **PGX** · Microbiology
Source: <https://www.510kdatabase.net/k183366/>**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	Dec 4, 2018
Decision date	Mar 6, 2019
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Genepoc, Inc.
Location	Quebec, CA
Contact	Dany Leblanc
510(k) history	5 submissions · 5 cleared · 2017-2019

CLINICAL EVIDENCE - NCT03422341**Validation of the GenePOC Strep A, C/G Assay for Detecting Group A, C and G β -hemolytic Streptococcus From Throat Swabs.**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	497 patients (actual)
Study sites	8 sites
Condition studied	Pharyngitis, Infective
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jul 11, 2018
Sponsor	Meridian Bioscience, Inc. (Industry)

Primary outcome

Performance characteristics of the GenePOC Strep A, C/G assay

Secondary outcome

Positive and Negative Predictive Values (PPV and NPV)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03422341