

K170558 revogeneMay 25, 2017
90 days to decisionK170558 · Product code: **OOI** · Microbiology
Source: <https://www.510kdatabase.net/k170558/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Real Time Nucleic Acid Amplification System (OOI)
Date received	Feb 24, 2017
Decision date	May 25, 2017
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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