

**K191957 BD MAX Vaginal Panel**Oct 21, 2019  
90 days to decisionK191957 · Product code: **PQA** · Microbiology  
Source: <https://www.510kdatabase.net/k191957/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vaginitis And Bacterial Vaginosis Nucleic Acid Detection System (PQA)
Date received	Jul 23, 2019
Decision date	Oct 21, 2019
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Geneohm Sciences Canada, Inc. (Bd Diagnostics)</b>
Location	Quebec, CA
Contact	Katie Edwards
510(k) history	4 submissions · 3 cleared · 2013-2019

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