

**K201017 BD MAX Vaginal Panel, BD MAX System, BD Molecular Swab Collection Kit**

Oct 18, 2021  
549 days to decision

K201017 · Product code: **PQA** · Microbiology  
Source: <https://www.510kdatabase.net/k201017/>

**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	Apr 17, 2020
Decision date	Oct 18, 2021
Days to decision	549 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 Life Sciences)</b>
Location	Quebec, CA
Contact	Katie Edwards
510(k) history	1 submissions · 1 cleared · 2021-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k201017/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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