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

CLEARED

Oct 18, 2021
549 days to decision

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

SUBMISSION DETAILS

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

Company	**Geneohm Sciences Canada, Inc. (Bd Life Sciences)**
Location	Quebec, CA
Contact	Katie Edwards
510(k) history	1 submissions · 1 cleared · 2021-2021