

K220407 Visby Medical Sexual Health TestMar 7, 2023
386 days to decisionK220407 · Product code: **QEP** · Microbiology
Source: <https://www.510kdatabase.net/k220407/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Nucleic Acid Detection System For Non-viral Microorganism(s) Causing Sexually Transmitted Infections (QEP)
Date received	Feb 14, 2022
Decision date	Mar 7, 2023
Days to decision	386 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Visby Medical
Location	San Jose, CA, US
Contact	Beth Lingenfelter
510(k) history	2 submissions · 2 cleared · 2021-2023

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