

**K243343 BD CTGCTV2**

Apr 22, 2025  
179 days to decision

K243343 · Product code: **QEP** · Microbiology  
Source: <https://www.510kdatabase.net/k243343/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Acid Detection System For Non-viral Microorganism(s) Causing Sexually Transmitted Infections (QEP)
Date received	Oct 25, 2024
Decision date	Apr 22, 2025
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bd Integrated Diagnostic Solutions/Becton,</b>
Location	Sparks, MD, US
Contact	Teresa Jennifer Sugumar
510(k) history	1 submissions · 1 cleared · 2025-2025

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