

K230956 BD Respiratory Viral Panel for BD MAX™ SystemJul 31, 2023
118 days to decisionK230956 · Product code: **QOF** · Microbiology
Source: <https://www.510kdatabase.net/k230956/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-target Respiratory Specimen Nucleic Acid Test Including Sars-cov-2 And Other Microbial Agents (QOF)
Date received	Apr 4, 2023
Decision date	Jul 31, 2023
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BD Respiratory Viral Panel-SCV2 for BD MAX™ System

APPLICANT

Company	Bd Integrated Diagnostic Solutions /
Location	Sparks, MD, US
Contact	Kathy Barnecut
510(k) history	1 submissions · 1 cleared · 2023-2023

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