

K240854 Accelerate Arc SystemSep 26, 2024
182 days to decisionK240854 · Product code: **QNJ** · Microbiology
Source: <https://www.510kdatabase.net/k240854/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mass Spectrometry, Microorganism Identification, Blood Culture (QNJ)
Date received	Mar 28, 2024
Decision date	Sep 26, 2024
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Accelerate Diagnostics, Inc.
Location	Tucson, AZ, US
Contact	Jack Phillips
510(k) history	2 submissions · 2 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	Precision For Medicine, Inc.
Contact	Jo-Ann Gonzales

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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