

K191514 CareStart Flu A&B PlusFeb 18, 2020
256 days to decisionK191514 · Product code: **PSZ** · Microbiology
Source: <https://www.510kdatabase.net/k191514/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Jun 7, 2019
Decision date	Feb 18, 2020
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Access Bio, Inc.
Location	Somerset, NJ, US
Contact	Sang Joon Han
510(k) history	3 submissions · 3 cleared · 2020-2025

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