

K183089 Air NextJan 2, 2020
422 days to decisionK183089 · Product code: **BZG** · Anesthesiology
Source: <https://www.510kdatabase.net/k183089/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Nov 6, 2018
Decision date	Jan 2, 2020
Days to decision	422 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nuvoair AB
Location	Stockholm, SE
Contact	Max Ladow
510(k) history	2 submissions · 2 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	Smith Associates
Contact	Yolanda Smith

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

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