

K183479 Asthma Monitor AM3Oct 3, 2019
290 days to decisionK183479 · Product code: **BZG** · Anesthesiology
Source: <https://www.510kdatabase.net/k183479/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Spirometer, Diagnostic (BZG)
Date received	Dec 17, 2018
Decision date	Oct 3, 2019
Days to decision	290 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eresearch Technology
Location	Philadelphia, PA, US
Contact	Kristin Feld
510(k) history	2 submissions · 2 cleared · 2014-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183479/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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