

K180487 Peak.meOct 26, 2018
245 days to decisionK180487 · Product code: **BZH** · Anesthesiology
Source: <https://www.510kdatabase.net/k180487/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Meter, Peak Flow, Spirometry (BZH)
Date received	Feb 23, 2018
Decision date	Oct 26, 2018
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Breathe Me, Ltd.
Location	‘Anana, IL
Contact	Yoram Levy
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Qsite
Contact	Yoram Levy

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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