FDA 510(k) Premarket Notification

K180487 Peak.me

CLEARED

Oct 26, 2018
245 days to decision

K180487 · 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	Ra'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